IN THE CIRCUIT COURT OF OHIO COUNTY,
WEST VIRGINIA

IN RE: TOBACCO LITIGATION
CIVIL ACTION NO. 00-C-6000

(MEDICAL MONITORING CASES)
(Judge Arthur M. Recht
Judge Tod J. Kaufman)

The deposition of NARESH C. GUPTA, M.D., taken upon oral examination, pursuant to notice and pursuant to the West Virginia Rules of Civil Procedure, before Johnny J. Jackson, Registered Diplomate Reporter and otary Public in and for the State of West Virginia, Monday, August 21, 2000, at the offices of Jackson & Kelly, First Floor, 6000 Hampton Center, Morgantown, West Virginia.

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(Deposition Exhibit No. 1 marked for identification.)
MR. WOODSIDE: This is Frank Woodside. We've been having some difficulty here in Morgantown getting into the conference call.
To make matters simpler here, why don't we have everybody that's on the phone identify themselves for the Court Reporter, and then we will start.
MR. NEWBOLD: This is Bill Newbold for Thompson Coburn, St. Louis, Missouri, representing Lorillard.
MS. SMITH: Christie Smith from Farrell, Farrell & Farrell, Huntington, West Virginia, representing Lorillard.
MS. KANDZARI: This is Pamela Kandzari representing Phillip Morris.
MR. PLESKA: P. Michael Pleska in Charleston, representing R. J. Reynolds Tobacco Company.
MR. WOODSIDE: Anybody else on the phone?
For those who are on the phone,

I'm Frank Woodside representing Brown & Williamson.
MR. FURR: I'm Jeff Furr representing R. J. Reynolds.
MR. HUGHES: Ben Hughes representing Liggett Group.
MR. MICHIE: Chris Michie representing Phillip Morris, Inc.
MS. CALLAS: Gretchen Callas for Brown & Williamson.
MR. CHERVENICK: Dave Chervenick representing the Plaintiffs.
MR. WOODSIDE: While we were waiting, the witness was sworn.

NARESH C. GUPTA, DEPONENT, SWORN

EXAMINATION

BY MR. WOODSIDE:

Q. Dr. Gupta -- Is that how you pronounce it?

A. That's correct.

Q. -- would you please give us your name and address for the record?

A. Yes. Naresh C. Gupta. My home address is [DELETED]

My office address is Health Sciences Center, Morgantown, West Virginia, 26506.

Q. Let me hand you a copy of the Notice of Depositions of Plaintiffs' Expert Witnesses, which I have had previously marked as Exhibit No. 1, and ask you if you have had an opportunity to see that before?

A. Yes, sir.

Q. That document requests that you bring certain materials with you. Have you done so?
A. I have my curriculum vitae and my report.
Q. Do you have any other documents which are responsive to this notice?
A. No.
Q. Let me go down the documents which I have identified there and ask you a number of questions about them.
Do you have a list of the cases in which you have previously testified as an expert at trial or by deposition?
A. I have not before testified in any case as an expert, but I have testified in cases as a

treating physician. So I did not bring those lists.
Q. I will get to that in a minute.
Do you consider that your curriculum vitae is responsive to No. 2?
A. Yes.
Q. With regard to No. 3, which requests any and all documents that you relied upon or reviewed in forming the opinions that you will render in this case, do you have any such documents?
A. I relied upon information that is in me, and borrowed from several journals. I like to read a lot of stuff and articles, and I don't necessarily make copies of these. There are some things that are digital in form. I just like to read in that form. So it was stuff for me, to bring the copies of the articles that I read a month ago, for example, or two months ago.
Q. I will get back to that in a minute.
With regard to No. 4, which requests any and all depositions, medical records, bills, receipts, hospitalization records, test results,

lab results, population data or other documents in your possession relating to the class representatives, any putative class member or members of this case.
Do you have any such documents?
A. No.
Q. No. 5 requests any and all documents in your possession which support or relate to the opinions that you will render in this case.
Is your response to my request for that information the same as your response to my request for information contained in No. 3 previously?
A. Pretty much so, yes, sir.
Q. No. 6 requests all of your files, including all notes, invoices, bills, phone logs, reports, correspondence, drafts, test results, and supporting raw data, or other documents which relate to this case.
Do you have any such documents?
A. I have my report that I brought.
Q. Did you bring everything you have in

that regard?
A. The expert report.

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Q. No. 7 requests any and all books, magazines, manuals, medical journals, articles, pamphlets, videotapes, photographs and literature which relate to or reflect the opinion that you will render in this case or which you have reviewed in connection with this case.
To the extent that you have any such materials, did you bring all of them with you?
A. I don't have all of them with me today. As I said, I just read a lot of stuff in the library.
Q. I believe I understand your position.
Let me explain what I'm going to do. I'm going to ask you a number of other questions, and then I'm going to have some specific questions which relate to this case and what you brought.
I think I have an understanding of what your situation is.
Where were you born, sir?
A. Born in India, New Delhi.
Q. What's your birth date?
A. 5/6/54.

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Q. As I understand the situation, you went to medical school in India?
A. That's correct.
Q. Thereafter, you took some general surgery training in India?
A. That's correct.
Q. Then came to the United States?
A. That's correct.
Q. Took some general surgery training at the Jewish Hospital is Brooklyn?
A. That's correct.
Q. I take it you did not finish that general surgery training program?
A. No. I got more interested in imaging, yes.
Q. How many years of training do you have in nuclear medicine?
A. Total of three years.
Q. That would be two years at State University of New York in Buffalo, or three years there?
A. Two years at State University of New York at Buffalo, and one year at the University of Pennsylvania.

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Q. You are board-certified in nuclear medicine?
A. That is correct.
Q. I understand that you have a certificate from the Board of Nuclear Cardiology?
A. I'm certified in nuclear cardiology.
Q. So you have two areas of certification in nuclear medicine?
A. Two separate areas; one in nuclear medicine, one in nuclear cardiology.

Q. I understand that you're licensed in West Virginia as well as a number of other states?
A. That's correct.
Q. At what hospitals do you currently have privileges?
A. Currently I have privileges only in Ruby Hospital, West Virginia University Hospital.
Q. How do you spell that?
A. West Virginia University Hospital is also called Ruby Memorial Hospital.
Q. You will have to pardon me. I'm not from this area. I'm from Cincinnati, and some things I may not know, and I just ask.

A. No problem.
Q. Have you ever been in the public health service?
A. No.
Q. In the two years before you started your nuclear medicine training at State University of New York in Buffalo, being 1983 to 1985, what did you do?
A. I was working in Wheeling Hospital, Wheeling, West Virginia.
Q. What did you do there?
A. I was working as a trauma surgeon.
Q. Were you in private practice or were you employed by the hospital?
A. Employed.
Q. So I take it that you worked there for two years, and then you decided to undergo additional training, but in the field of nuclear medicine?
A. That's correct.
Q. At the current time you are professor of radiology at West Virginia University?
A. That is correct.
Q. That would be in the Division of Nuclear

Medicine?
A. The Division of Nuclear Medicine is part of the Department of Radiology.
Q. Besides the academic position you have at West Virginia University, do you have any other academic positions?
A. I don't know what you mean by that. Affiliations and institutions, or serving on committees or . . .
Q. I will rephrase my question.
Other than your academic position of being professor of radiology and director of the Division of Nuclear Medicine and the PET center at West Virginia University, do you have any other professorships, assistant professorships, et cetera, at any other academic institutions?
A. No.
Q. What professional journals do you regularly receive and review?
A. I'm a reviewer in Journal of Nuclear Medicine, reviewer in Chest. On occasion I review articles from Cancer, Clinical Nuclear Medicine.

The other part of the question was what

journals I receive?
Q. Yes.
A. There are some journals I subscribe, and lots of them I go to the library and read. My interest is in Chest, so the journals will vary a lot. Do you want me to mention some of those?
Q. Please do.
A. Radiology, General Nuclear Medicine, Chest, General Clinical Oncology, General Thoracic Cardiovascular Surgery, Radiologic Clinics of North America, Seminars on Nuclear Medicine.
Those are the ones that come to mind at this time.
(Deposition Exhibit No. 2 marked for identification.)
Q. Before I forget, I'm going to hand you what has been marked as Exhibit No. 2, which at the top of the first page is entitled Expert Report of Naresh C. Gupta, M.D.
Can you identify that, Doctor?
A. Yes.
Q. Is the first part of this document the report that you authored in this case?

A. Can I look through it?
Q. Oh, certainly. Please do.
A. Yes. It is.
Q. That is the report that you authored and signed on August 3, 2000?
A. That's correct.
Q. Is the second portion of this document a copy of your curriculum vitae?
A. That's correct.
Q. Is this curriculum vitae up to date, or at least reasonably so?
A. I could probably add a couple more articles in it, but it is reasonable, like you said.
Q. In the first portion of Exhibit 2 entitled Expert Report of Naresh C. Gupta, M.D., have you set forth the opinions which you anticipate that you would give in the litigation that brings us here today?
A. That's correct.
Q. May I assume that you have no other opinions that you would anticipate giving in this case, that is, no opinions other than those which you have set forth in your report?

A. That depends. It is tough to put all the opinions that I have in the report. I mean, there may be some that missed out that I have.
Q. As we sit here today, do you know of any additional opinions that you will be giving other than those that are set forth in your report that is labeled Exhibit 2?
A. I try to make as much inclusive of my ideas as possible.
Q. So, as we sit here today, you believe the report is complete?

A. I believe I could not swear.
Q. As we sit here today, you do not know of any omissions from your report which currently exist; correct?
A. I don't know at this time, yes.
Q. What you mean is you don't know of any omissions at this time; correct?
A. That's correct.
Q. Let me follow up on your testimony regarding your role as a reviewer for certain professional publications.
With regard to your review of those documents, were you serving as what is known as

a peer reviewer?
A. That is correct.
Q. Would you explain to me what you consider your role to be when you peer review documents for publication in professional journals and publications?
A. A reviewer typically has to screen the quality of the manuscripts and render his or her opinion regarding whether they are worthy of publication in the journal or not.
Q. Is it true that when articles are peer-reviewed prior to publication it is to insure that they are of a professional quality, that they are well done and reflect research or work that has been performed in accord with the tenants of good science?
A. Relatively so. What we do as a reviewer is we score the articles rather than give them it's good or it's not good. The articles are scored in different categories in quality, in innovation, in organization, and any other flaws. There are more than one reviewer that reviews an article, and the editor-in-chief makes the final decision.

Q. Is the purpose of the practice of peer review to make sure that, among other things, articles which get published in peer-reviewed professional journals are scientifically valid and accurate?
A. The reviewer looks at all the information and critiques it. Again, the quality is a relative term. How good an article is is a relative term. But a reviewer looks at it and scores, keeping all things in mind. One of those is validity of the data and the scientific merit.
Q. So one of the things the reviewers attempt to do is to make sure that articles which are published are scientifically valid? That would be one of the objectives; correct?
A. Those are the objectives of the editorial office of the journal, and how they bring about the process of review, which helps them ensure that.
Q. Would you please refer to page 20 of your curriculum vitae? I see there in the middle of the page there is a section entitled "Research Grants" bearing Roman numeral XI.

Do you see that section, sir?
A. Yes, I do.
Q. And then A(1) reads, "Principal investigator on, Combined modality (CT+PET) model for efficient screening of lung cancer-screening."
Do you see that, sir?
A. Yes.
Q. That indicates that this is an application for a research grant which is to be submitted for the National Cancer Institute for funding in September of the year 2000 wherein you seek $900,000; correct?
A. That is correct.
Q. Has that grant application been submitted to the National Cancer Institute yet?
A. Not yet.
Q. Would you please tell me what the subject of that grant application is, in other words, what's the protocol, briefly?
A. I probably should not comment on something that's not completed or submitted yet. It's still in the process of being completed.

Q. Why should you not comment on it?
A. Because it's subject to changes among all the investigators.
Q. Who are the other investigators?
A. That could also change, but who are the ones right now?
Q. Yes.
A. Dr. John Rogers.
And a statistician, Dr. Jerry Hobbs.
Q. At this point in time at least, I do not have as an objective obtaining the details of this particular proposed grant application. I may at point in time. But at this point in time I do not. So if you could give me a two- or three-sentence overview of what you're contemplating doing, then I will pass on to other questions. I don't guarantee I won't come back to it, but it may well be that I won't.
A. As I said, we are still looking at revising this application. If I tell you something now, it may totally be changed tomorrow before submission. So I don't really see much point in that.
Q. When are you planning on submitting this

grant application, approximately?
A. We are trying to submit it at the end of September, but if we are not able to finish it it may be in the next cycle, which would be January of 2001.
Q. Let me go at the issue this way: In this particular litigation that brings us here today, you are proposing that there be a combined modality consisting of CT and PET scan for screening of lung cancer; correct?
A. That's correct.
Q. Is the proposed medical-monitoring

program using these combined modalities that you have proposed in this litigation similar to the combined modality model for efficient screening of lung cancer that you contemplate will be the subject of your request for National Cancer Institute funding?

A. I think two are different things. Our goal of submitting the proposal to NCI is purely for research purposes.

The model that I'm proposing here for monitoring is here, that's for implementation.

Q. Are they basically the same programs?

A. They probably are based on a fundamental same hypothesis and similar observations.

Q. Those hypotheses and similar observations would be what?

A. Those are that at this time of technological advancement this represents the best model for screening in the State of West Virginia.

Q. With regard to the combined modality model for screening, using CT and PET scans, that you have proposed in this litigation, have there previously been reported any randomized controlled trials establishing the validity of that combined modality screening program?

A. There is no need to do a randomized controlled study. That was one of the major mistakes that was done previously.

There is a big consensus building up. There are several review articles being published that randomized control trials have several disadvantages. With the evidence that is there at this time in the literature, it is sufficient evidence for one come to the conclusion that this now at this time is enough

information for this to be the best model for screening.

Q. Excuse me, sir. I didn't ask that question.

Are there any such randomized control trials?

A. Using what?

Q. Have there been any randomized controlled trials regarding the validity and efficacy of combined modality using CT and PET for efficient screening of lung cancer patients? Sir, that requires a "yes" or "no".

MR. CHERVENICK: I object to that.

Q. Then you may explain.

MR. CHERVENICK: He can answer however he feel it has to be answered.

A. I cannot answer yes or no. I have to qualify the answer, if you will let me please.

Q. I will.

A. There is a non-comparative study published in Lancet that was published about a year ago, I think, approximately.

There are several studies published

looking at the validity of CT for lung cancer-screening, which all point out that this is perhaps a better model for screening non-comparative study design than a randomized clinical trial for the lung cancer-screening.

Also, in the recent international conference of lung cancer-screening that was held in New York, the consensus was a randomized clinical study would not add any further information. The evidence is already here. The CT scanning should be used for lung cancer-screening, and is extremely helpful, and is the modality of choice for lung cancer-screening.

To that we also add all the literature that's already published in several journals proving that PET is an excellent complimentary modality to CT. So all we are doing is taking the information that is already there in the literature and putting it together, that is, CT plus PET. That's the combined modality model.

Q. The study which you report from The Lancet is the study reported by Claudia Henschke and others; correct?

A. That's correct.

Q. That study did not use PET scan; correct?

A. It did not.

Q. In responding to my question, can you give me any citations in the scientific literature to any randomized controlled trials evaluating the validity and efficacy of combined CT and PET scanning for the efficient screening of lung cancer?

A. I just mentioned randomized control trials have been heavily criticized. They are not the trials to be used for screening in general, number one.

And, number two, as I mentioned, there are hundreds of citations in the literature of using PET scanning in lung cancer, detection of lung cancer by PET scanning.

There are several citations available in the literature now using CT scanning for screening of lung cancer.

So all I'm doing is combining the two information that is already there, and optimize the model which is best suited.

Q. If I understand what you're telling me, you are telling me that there are studies out there involving CT scanning and studies out there involving PET scanning, but you are unable to give me any references to any studies involving the combined CT and PET scanning for screening of lung cancer; correct?

A. There are citations available using both modalities for detection of lung cancer.

Q. For randomized control trials?

A. I already said randomized control trials have been heavily criticized as being more negative than positive and does not provide

useful evidence for lung cancer screening. It is included in the consensus statement of the international conference, for screening of lung cancer.

Q. Do you know of any cohort studies involving combined CT and PET scanning for efficient screening of lung cancer patients?

A. I know of studies using both modalities for detection of lung cancer.

Q. Do you know of any cohort studies involving both modalities together?

A. For lung cancer detection?

Q. Yes, sir.

A. Yes.

Q. Name one.

A. We have published ourselves studies with combined PET and CT in detection of lung cancer.

Q. For screening?

A. Not for screening, for detection. I said detection for lung cancer.

Q. Do you know of any for screening?

A. It does not matter. In screening what we are doing is detecting lung cancer.

Q. I take it that you're unable to identify any cohort studies involving the use of CT and PET as a combined modality in screening; correct?

A. If I were asked, What do you mean by screening, detection of lung cancer is embodied in the term "screening." That's what you do when you screen patients.

As I mentioned, there has been no publication -- I already said that -- in randomized control trials. But those trials have been heavily criticized by all these

well-respected people around the country and internationally who have published separate studies on CT screening.

There's a lot of studies already available for PET scanning. There are already studies available for PET and CT scanning for detection of lung cancer. All one has to do is put all of this together and the answer is already there.

Q. Do I understand that your testimony would basically be the same with regard to cohort studies and case-control studies, that is, that there are not any such studies dealing with the combined use of CT and PET for efficient screening of lung cancer, but that even if there were, those tests would be criticized, those studies would be criticized; correct?

MR. CHERVENICK: I object to the compound question.

MR. WOODSIDE: That's a good objection.

MR. CHERVENICK: That's not a fair characterization.

A. I don't think that's my implication. I

think the wording you are saying is quite different from what I'm saying.
Q. However, as we sit here today, you cannot give me the citations for any cohort studies or case-control studies using the combined CT and PET scan model for screening of lung cancer; correct?
A. There are studies showing CT and PET. When used together for detecting very early lung cancer provide very high accuracy, specificity, and sensitivity.
Q. I'm going to ask you some general questions about your background and your expertise, and then I will come back to your report in just a minute.
You are not formally trained in hematology and oncology; correct?
A. That's correct.
Q. You are not formally trained in pathology, epidemiology, toxicology or pharmacology; correct?
A. That is correct.
Q. While you have an academic position in

the Department of Radiology, you are not a radiologist; correct?
A. I'm not a board-certified radiologist, but we interpret the studies all the time.
Q. You are not formally trained in psychiatry, addiction medicine, with a diagnosis and treatment of dependency disorders; correct?
A. That is correct.
Q. You are not an expert in the design, manufacture, distribution or sale of cigarettes or other tobacco-containing product; correct?
A. That's correct.
Q. You are not formally trained as a cardiologist in that you are not board-certified in internal medicine or the subspecialty board of adult cardiology; correct?
A. That's correct.
Q. Do you consider any particular textbooks to be authoritative in the field of general medicine?
A. In general medicine, I take it, internal medicine?
Q. Yes. Such as Cecil or Harrison or something?

A. Yes, I would regard Harrison's books pretty highly.
Q. How about Cecil?
A. Both.
Q. Do you have any texts that you consider to be authoritative in the field of pathology or lung pathology in particular?
A. No. That's not my field, so I will not comment.
Q. How about in the field of nuclear medicine?
A. There are several books.
Q. Could you give me a list of two or three of them?

A. There is a book by Dr. Henry Wagner, a textbook on nuclear medicine.
Q. Excuse me. Henry Wagner?
A. Yes.
There are quite a few others I don't remember at this time.
Q. Fair enough.
Do you have any textbooks that you consider to be authoritative in epidemiology and biostatistics?

A. That's not my expertise.
Q. So I gather the answer is you are not able to tell me any textbooks which you consider to be authoritative in that field.
A. I will not comment on something that is outside my field.
Q. Fair enough.
With regard to CT scans and spiral CT scans that are performed at your institution, I assume that because you're not board-certified in radiology you are not the individual who actually does the formal readout of those; correct?
A. That is correct.
Q. At West Virginia University, I assume that there's a large radiology staff.
A. That's correct.
Q. Are there any particular radiologists on staff at West Virginia University Medical School who do the CT work?
A. There are quite a few, a number of radiologists who read formally CT scans of the chest and x-rays, although when we are doing PET scanning we always look at the CT scans of the

patients.
Q. But you are not the individual who formally reads out the CT or the spiral CT scans; correct?
A. That is correct.
Q. When you read them as part of your clinical work or your research, you also read them in conjunction with a radiologist who then actually does the formal readout; correct?
A. Of what?
Q. The CT or spiral CT.
A. When I read the CT scans? I'm sorry. I lost you a little bit.
Q. Fair enough. Let me back up.
There will be occasions where there will be nuclear medicine patients with whom you are specifically involved in your area of expertise who will also have CT or spiral CT scans; correct?
A. That's correct.
Q. In those patients, the formal readout of the CT scan or the spiral CT is performed by a radiologist, as opposed to yourself, although you may actually look at and comment upon and

read the CT or the spiral CT; correct?
A. In almost all cases that undergo PET

scanning in our center, we review the CT scans on the computer and on the films. On the formal readout, you are correct, has been read out by somebody else.

Q. That would be a radiologist; correct?

A. That is correct.

Q. Thank you.

Do you smoke?

A. No.

Q. Have you ever?

A. No.

Q. Does your spouse smoke?

A. No.

Q. Do you have any family members who smoke?

A. Not that I know of.

Q. Do you or your spouse or your children have any history of smoking?

A. Do you mean that have ever smoked?

Q. Yes.

A. I don't think.

Q. I may have asked this before. If I did,

I apologize for being repetitive.

You are not an expert in cigarette design and warnings; correct?

A. That is correct.

Q. Do you recall that early on when we were going over the notice I had discussed with you the extent to which you had been a witness in prior litigation. I believe that you indicated that you had never served as an expert witness before; is that correct?

A. That is correct.

Q. Have you had occasion to be deposed in prior litigation?

A. I have given depositions in several cases, yes.

Q. What was your role in those cases? And let me tell you what I'm looking for. Were you involved as an individual who had been involved in the care, treatment and diagnosis of someone that was involved in the case?

A. That's correct.

Q. Do you know about how many of those times there were?

A. If I have to guess, I probably would be

wrong. But there are quite a few, maybe 10 to 15 times.

Q. How many of them have been in West Virginia, that is, since you have been in West Virginia as opposed to when you were at Creighton or in your training?

A. I would say there were a few in Omaha, and most of they are in West Virginia.

Q. Are you able to give us any of the names of any of the cases that you have been involved in?

A. No.

Q. Do you know any of the lawyers that were involved?

A. Their names I don't remember offhand.

Q. Do you remember when the last time was that you were deposed, approximately?
A. Yes. Last time was about a month ago. I think it was with a firm in Charleston. I remember the name of the attorney if you want.
Q. Yes.
A. Michael Bee.
Q. Could you spell that for me?
A. B-e-e is the last name. Michael, first

name.
Q. Any others that you can recall?
A. No.
Q. Are you a member of any antismoking organizations?
A. No.
Q. Do you think cigarettes should be banned, or don't you have an opinion on that?
A. I think they should be banned, but that's my personal opinion.
Q. Do you understand that they are legally on the market?
A. Yes.
Q. Have you ever been involved in any antismoking activities?
A. No.
Q. Why do you think cigarettes should be banned?
MR. CHERVENICK: I'm going to object to the question as irrelevant and beyond his area of expertise.
A. They serve no use and they cause several harms.
Q. With regard to the lawsuit that brings

us here today, do you know who the Plaintiffs are?
A. I know Blankenship. I think the case is titled that way. That's about the only one I know. I know it's a class action suit.
Q. Do you know anything about Christa Blankenship, one of the Plaintiffs?
A. Do I know anything about her as a person?
Q. Yes.
A. No.
Q. Let me tell you what I'm trying to do, and then maybe I can make some of this a little bit shorter.
I'm trying to find out what you know as well as what you don't know, so that I know where to direct my questions. And I'm trying to confirm where you have opinions and what those are so that I can ask you questions about those things, and then make sure of areas in which you don't have opinions so that I am comfortable that I have covered the waterfront, so to speak.
It doesn't require any response. That's just what I'm up to. Okay?

A. Okay.
Q. The two named Plaintiffs in this case are Christa Blankenship and Mae Sibo. I assume

that with regard to those two women that you do not have any particularized knowledge about them individually; correct?
A. That's correct.
Q. Indeed, in this case, with regard to those two women individually, you will not be offering any opinions with regard to them; correct?
A. I'm offering opinions concerning lung cancer-screening, and that's what they are involved in.
Q. There's no trick to this. The opinions that you have are general or broad, which are not limited to or directed specifically at Mae Sibo or Christa Blankenship; correct?
A. If they are involved in my opinions on lung cancer-screening, then indirectly it would be. But not directly as a person.
Q. I'm sorry. What was the last thing?
A. My opinions are not based on those two individuals as persons, based on lung

cancer-screening.
Q. Let me follow up to make sure of a couple of things.
You have never read the Third Amended Complaint in this case; correct?
A. Yes.
Q. You have not read the depositions of Mae Sibo or Christa Blankenship; correct?
A. Yes.
Q. Have you read the depositions of any of the Plaintiffs' experts in this case?
A. Yes. I read the deposition of Dr. Burns.
Q. Have you read any others?
A. No.
Q. Have you read any reports of any of the Plaintiffs' experts in this case?
A. Dr. Burns.
Q. I may have asked you this before. If I did, I apologize.
I assume from what you said you have not read any of the medical records of either Mae Sibo or Christa Blankenship; correct?
A. That is correct.

Q. As we sit here today, you do not have any knowledge about the medical history or current condition of either Mae Sibo or Christa Blankenship; correct?
A. That's correct.
Q. Have you had any personal communications with Dr. Burns or any other Plaintiffs' experts in this case?
A. No.
Q. With regard to this litigation, have you read any of the Surgeon General's reports regarding smoking and health?
A. No.
Q. Have you read any books or media materials -- which I'm not referring to professional publications -- dealing with

cigarette-smoking or tobacco companies?
A. Not any books especially with reference to them in articles.
Q. The articles you're referring to would be scientific articles?
A. That's correct.
Q. I'm differentiating scientific and professional journals from what I will call lay

or historical materials.
Do I understand that other than the scientific or professional journals and materials you have read where they may have been references to tobacco companies and smoking and health litigation, you have not reviewed or read or relied on any other types of materials which may relate to tobacco companies and smoking litigation; correct?
A. That is correct.
Q. Have you ever had any communications with any tobacco companies?
A. No.
Q. You are not an expert on addiction or smoking-cessation programs; correct?
A. That's correct.
Q. Do you consider that smoking is a matter of personal choice?
A. No. I think it causes harms to others, so it is not just a personal choice.
Q. But with regard to the individuals themselves that smoke, is it a matter of personal choice?
A. So far. But it probably should not be.

Q. Why do you say that?
A. Because if you look at all the harms it causes to others, without their choice.
Q. Let me tell you what I'm going to do. I'm going to go through your report. I'm not actually going to invite you to look at my notes, but as you can see, I have made a lot of notes on my copy of your report. To some extent I'm going to go through all those things with you, and then when we get done I will have a few other questions to ask you.
Do you have your report, which would be the first portion of Exhibit 2, in front of you?
A. Yes.
Q. Who wrote this report?
A. I wrote it.
Q. Were there any other individuals who had any input in the writing of this report?
A. Obviously, the knowledge that I have is based on what I read and what I have gathered from interacting with several people around my career.
Of course, I talked to the attorneys about what kind of report I'm supposed to write.

Q. Are any of the portions of this report similar to the language contained or proposed to be contained in the grant application to be submitted to the National Cancer Institute for

funding of the combined modality CT and PET for efficient screening?
A. Both of these, the report and the applications are written by me. I'm the first author.
So it is based on the same knowledge that I have. So I can't see how they would not be common things if it's the same person writing both things on a similar topic.
Q. If I understand you correctly, then there is similar language in this report as will be contained in the NCI grant book; correct?
A. I didn't say that.
Q. What did you say?
A. What I'm saying is, I wrote both these articles separately. But both these articles are based on the same knowledge. It's the same person writing. I cannot avoid having exactly the same things come in two different . . . because they are concerning the same topic.

Q. They are concerning the proposed combined modality of CT and PET for efficient screening of lung cancer; correct?
A. Yes.
Q. Did Dr. Rogers participate in the writing of your expert report in this case?
A. No.
Q. Did anybody else at West Virginia University participate in the writing of this report?
A. My secretary. But not otherwise.
Q. If you go down the first paragraph it says, "I, along with coinvestigators, pioneered the use of Positron Emission Tomography for its use in diagnosis of early lung cancer."
Which coinvestigators are you referring to?
A. Can I ask you to look at my CV?
Q. You surely can.
A. That would be easier rather than me mentioning the names. They are all mentioned in the reference number. I will give you the number. Article No. 14.
Q. Excuse me. Could you give me the page?

A. Page No. 7 on my CV, No. 14.
Q. Do you consider the information and materials set forth in Article 14 on your curriculum vitae to be a screening or medical-monitoring study?
A. It is detecting lung nodules. That's what we do in screening. So the information that is published in that article is the basis.
(Reporter's Note: Bill Newbold signed off at this point.)
BY MR. WOODSIDE:
Q. Doctor, would you tell me what your definition is of a screening program?
A. The screening program is aimed at detecting very early disease in asymptomatic high-risk population so that there is maximum chances of cure.

Q. Do you distinguish a screening program from a medical-monitoring program?
A. A medical-monitoring program does not necessarily have to be in a high-risk population and doesn't necessarily have to be in an asymptomatic population, as I understand. Again, I'm not an epidemiologist.

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Q. Would you agree that a screening test must be able to detect the target condition earlier than without screening, and with sufficient accuracy to avoid producing large numbers of false positive and false negative results?
A. The screening program should be able to detect disease in people above a minimum threshold, which is more than will be detected without screening, and would maximize the chances of treatment without having a significant number of false positives or false negatives, yes.
Q. With regard to screening of past or present smokers, which individuals should be screened?
A. As I mentioned in my report, we are recommending lung cancer-screening in subjects with more than 50 years of age and a 10-pack-year history.
Q. For what reason have you recommended screening in individuals who are more than 50 years of age and with a 10-pack-year history of smoking or more?

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A. If you look at the incidence of lung cancer, how it is related to the duration of smoking and the age, those are the two major risk factors.
The studies have shown that individuals who have smoked for more than 20 years have had statistically significantly higher incidence of lung cancer. Furthermore, the incidence of lung cancer starts to rise at age 40 onwards.
Q. It is true, is it not, that there is no data showing that there is a statistically significant increase in the development of lung cancer for individuals who have smoked less than 10 pack-years; correct?
A. There is data showing that there is increased risk of lung cancer. It has not reached statistical significance, it has not been shown that it has not reached statistical significance in less than 10 pack-years. That does not mean there is no increased risk.
Q. But it also does not mean that there is an increased risk; correct?
A. Again, when we are talking about risk we also have to understand what the screening

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program is aimed at. In the screening program you want to pick up this very early on. If you look at the history of lung cancer, how it develops, you want to actually pick up five years earlier than the incidence of lung cancer

that shows up without screening.
So if you look at those statements, then screening, it could possibly be argued that it might be done in five pack-years.
I don't know if I make myself clear.
Q. You said it could possibly be argued. You yourself are not making that argument, are you, sir?
A. I'm not an epidemiologist, but I have seen epidemiologists use that argument.
Q. To the best of your knowledge, there is no data showing a statistically significant increase in the risk of lung cancer for individuals who have smoked five pack-years or less; correct?
A. There is increased risk, but it may not have reached statistical significance. Again, that statement, you have to understand what the statement implies in terms of the screening

program. The aim of the screening program is backtracked before the disease has time to grow and manifest clinically.
Q. Just so the record is clear, and that I understood your answer, you yourself do not know of any studies showing a statistically significant increase in the risk of lung cancer in individuals who have smoked five-pack-years or less; correct?
A. I'm not aware of it. I'm not saying there is no such study.
Q. But you don't know of any?
A. Yes.
Q. Would you please look down at paragraph No. 3 on page 1 of your report? The first sentence says, "Early diagnosis of lung cancer has been a challenge for years."
Did I read that correctly?
A. "Has been a challenge for several years."
Q. I'm sorry.
"The lung cancer mortality and survival rates have not changed significantly over the years despite advances in the surgical

techniques and new treatment drugs."
Correct?
A. That's correct.
Q. How do you define mortality rates?
Let me tell you what I'm going to do. I'm going to ask you first to define mortality rates, and then I'm going to ask you what you mean by survival rates. I'm going to ask you to define both of those. If you care to do them at the same time, that would be fine by me.
A. Mortality rate is looking at the death rates due to the disease.
Q. And survival rates?
A. Survival rates are looking at subjects who suffer from the disease and have survived the disease, and these are often reported as two years mortality rate or five years mortality rate. A lot of times a lot of people report

them per 1,000 or per 100,000.
Q. Are you familiar with the term "lead-time bias"?
A. Lead-time bias?
Q. Yes, sir.
A. I have heard of it.

Q. Do you know what it is?
A. Again, I'm not an epidemiologist. But I think what it means is, if you detect the disease in the asymptomatic stage and treat it, then you may get a bias because it has not had time to develop clinically. So the rates might be different than if the disease would have gone by itself and manifested clinically.
Q. You're not sure about that, are you?
A. No.
Q. Mortality rates are generally expressed in mortality per 1,000 person years; correct?
A. Yes.
Q. Do you know of any studies published in the scientific literature demonstrating that CT scanning decreases the death rate?
A. A study from Claudia Henschke. That's a difficult question. CT scanning is not a treatment. It's a diagnostic modality. How can a diagnostic test directly change -- it's an indirect way, and you can't really have a study looking directly at the impact of a diagnostic test unless you have a very long followup.
You also have to remember the spiral CT

is a relatively new advent. It wasn't even there until two or three years ago. So for one to have the data available, you have to wait at least five years.
(Deposition Exhibit No. 3 marked for identification.)
Q. Doctor, I'm going to hand you what's been marked as Exhibit 3, from the National Cancer Institute, National Institutes of Health. It's a National Cancer Institute press release, "Spiral CT Scans for Lung Cancer."
Have you had occasion to see that previously, Doctor?
A. Yes.
Q. This is a press release which relates to spiral CT scans for lung cancer; correct?
A. That's correct.
Q. Would you go to the end of the first paragraph, the last sentence. Actually, let me read the last two sentences.
"Spiral computed tomography (CT or CAT) scans are being advertised as a new way to find early lung cancer in smokers and former smokers. However, questions about the

technology's risks and benefits remain unanswered."
First of all, did I read that correctly?
A. That's correct.
Q. Sir, do you agree with that statement?
A. You have to look at the big picture,

though. And the consensus of opinion among people, among the investigators who work in this area, are spiral CT's have significant advancement and improvement over the prior tests that have ever been used for lung cancer-screening.

There are some questions remaining, yes. But they are being answered by several of the articles that are being published almost every month in several journals. No modality is perfect in the field of medicine, that I know.

Q. So you would agree that there remain questions about the risks and benefits of CT; correct?

A. Do I agree?

Q. Yes.

A. No. I'm convinced that CT scanning itself has proven itself to be the best modality

so far available with significant benefit when it's used for lung cancer-screening. Now, some of the investigators may have some questions. It's possible.

Q. I will get back to that in just a moment.

Would you look at the next paragraph?

"Promising evidence from several studies shows that the scans can detect small lung cancers. But detecting these early tumors has not been proven to reduce the likelihood of dying from lung cancer, the gold standard for any cancer-screening test."

First of all, did I read that correctly?

A. That's correct.

Q. Let me break it down, because there are several statements in there.

Do you agree, sir, that the gold standard for any cancer-screening test is whether or not the likelihood of dying from lung cancer has been reduced?

A. You have to really look at that in the context of the big picture. If you look at, for

example, the study that was published by Claudia Henschke, 80 percent of cancers that were treated in that study were resectable.

Now, if you just look at those cancers they treated with resectability, the cure is in the literature. It's already there. It's 75 percent, 70 percent. That means 75 percent of the patients in that study published by Claudia Henschke, at least, are going to survive five years. So, yes, I am convinced there is already enough evidence.

But, again, you have to wait for five years before the five-year survival rate. But you just have to look at the big picture of what the death rates are, what the survival rates are, when the disease is treated so early in the stage.

Q. Sir, whether those patients are going to live five years or not, as we sit here today,

you do not know, do you?
A. All you need to do is use the information that's already available. The information says that if the cancer is treated in stage I, when it's resectable, the survival

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rate is 70 to 80 percent.
But if the disease presents later -- and that has been the problem with lung cancer, it is not detected early. When it is detected, it is a very advanced disease, the survival rate is very poor, 10 to 15 percent.
It's already been shown that with CT scanning you will pick up very early in stage I. Most of the cancers that were picked up in her study in, Claudia Henschke, were stage I. So there will be prevention of deaths.
MR. FURR: He didn't answer the gold standard question.
Q. Let me go back and ask you a couple of questions.
First of all, if you would look at this Exhibit, No. 3, it says, "The gold standard for any cancer-screening test is whether there has been a reduction in the likelihood of dying from lung cancer."
Do you agree with that statement, sir?
A. Which statement are we talking about, again? I'm sorry. In the second paragraph?
Q. Yes.

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A. "But detecting these early," the statement starting with that?
Q. Yes, sir. Do you see that sentence?
A. Yes.
Q. I'm going to read the sentence. Then I'm going to ask you a couple of questions again. But I will be very pointed.
The sentence reads, "But detecting these early tumors has not been proven to reduce the likelihood of dying from lung cancer, the gold standard for any cancer-screening test."
First of all, did I read that correctly?
A. You read it correctly.
Q. Do you agree, sir, that the gold standard for a cancer-screening test is whether there is a reduction in the likelihood of dying from lung cancer?
A. Yes.
Q. You agree with that; correct?
A. Yes.
Q. I will represent to you, I will come back to the Claudia Henschke study later. I'm not sure. There were some things that we could follow up on, and I will get back to that in a

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few minutes.
Continuing on in paragraph three, I'm just going to refer you to the next to the last sentence.
"Thus most investigators agree on the need to detect lung cancer very early to improve the patient treatment outcome in lung cancer."

Do you see that sentence?
A. That is correct.
Q. What do you mean by the term "patient treatment outcome"?
A. How patient do on treatment, in other words, when the patient is being treated what is the survival rate and what is the death rate.
Q. The next sentence says, Tumor size at time of detection significantly influences survival for patients with lung cancer."
First of all, did I read that correctly?
A. Yes.
Q. What is the basis for that statement? In other words, what studies do you rely on, if any?
A. There are several, several studies

looking at the size of the tumor, when the tumor is less than two cm, when the tumor is less than three cm or greater than three cm, looking at longitudial study, looking at the survival rates.
And there is unequivocal evidence that if the tumors are detected when they are larger than two centimeters they have poorer survival rates as compared to when they are detected at less than two cm.
Further, there are studies showing when the tumors are detected when they are more than three cm, they do much worse than when the tumors are detected at less than three cm.
Q. There are also studies showing that with regard to lesions less than three centimeters, small nodule detection with screening CT may not significantly improve lung cancer mortality; correct?
A. No. I don't agree with that. I can cite you several references which say the lung cancer survival rate is improved and mortality decreases when the tumors are detected when they are less than three CM versus when they are

detected more than three centimeters, sir.
(Deposition Exhibit No. 4 marked for identification.)
Q. Doctor, I'm going to hand you what's been marked Exhibit 4, which is an article by Edward E. Patz, Jr., M.D., and others, entitled, "Correlation of Tumor Size and Survival in Patients with Stage IA Non-small Cell Lung Cancer," and ask if you have had an opportunity to review that, sir?
A. I looked at that article. I don't think I have read it in detail.
Q. Let me ask you a couple questions about it. Would you please look at the abstract which appears on the first page, at the top.
Do you see that, sir?
A. Yes.
Q. Under "Objective" it says, The purpose of this study was to determine the relationship between tumor size and survival in patients with

stage IA non-small cell lung cancer (non-small cell lung cancer, i.e., lesion -3 cm)."
First of all, did I read that correctly?

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A. Yes.
Q. Sir, when you looked at this article earlier, did you understand that that was the purpose of the study that is reported by Dr. Patz and others?
A. Yes.
Q. Now, sir, if you would, go down to the "Conclusions" section. I'm going to read the conclusions section, and then ask you one or two questions about it.
"This study confirms stratifying patients with stage IA non-small cell lung cancer in the same TNM classification, given no apparent difference in survival. Unfortunately, these data caution that improved small nodule detection with screening CT may not significantly improve lung cancer mortality. The appropriate prospective randomized trial appears warranted."
First, did I read that correctly, sir?
A. Yes.
Q. Sir, you will note thereafter, still in the abstract at the top, this is an article from Chest 2000; correct?

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A. Yes.
Q. These authors conclude that improved small nodule detection with screening CT may not significantly improve lung cancer mortality.
Is that what they concluded?
MR. CHERVENICK: I'm going to object to the question, because Dr. Gupta has indicated he has not read this paper in detail and is, therefore, not familiar with it.
Q. First of all, is that what they concluded?
A. This is the first time I am looking at this. But what you're saying, I agree that's in the conclusion.
But just so the whole thing is not misinterpreted by a third person, I will point your attention to the second paragraph on the same page on the article that you're showing me.
Q. Excuse me. Are you talking about at the bottom?
A. Yes, at the bottom, starting with, "While several studies have demonstrated that patients with T1 lesions and stage IA disease do

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better than patients with T2 lesions and stage IB disease."
That's an important statement right there where the author himself is saying that several studies have already shown that patients with T1 lesions and stage IA disease do better than patients with T2 lesions and stage IB disease.

Now, what the authors are further looking at is within stage IA disease. So he's talking about specifically a narrow population of patients which were present in stage IA. That's number one.

Number two, this is a retrospective study which they are looking at, and where they do not find statistical significance in tumors less than three cm versus more than three centimeter.

Q. Sir, in this article Dr. Patz and others are talking about tumor size of less than three centimeters, which is the size of the tumors you would hope to pick up with combined CT and PET scanning; correct?

A. Yes.

Q. In those tumors they did not find improved mortality with the finding of smaller nodules; correct?

A. What this article is saying, even though I have not read the article in great detail, number one.

Number two, it's a retrospective study.

But still looking at the article at its face value, this article makes no implication whether there is any difference in the survival rate when the tumors are detected stage IA versus IB versus IIA.

Our goal in screening is to pick up the disease very early on in stage IA. Now, what these people are looking at is within the stage IA differences in the different sizes versus the survival rate, just so that is very clear.

Q. And they also recommend the performance of prospective randomized trials; correct?

A. That is to answer what question? The question to be answered is within the stage IA if the size makes a difference, although I don't agree with the results of this article. But even if hypothetically we consider this be to

true, still it does not have any ramifications on what we are trying to do, because our goal is to pick up tumors in stage IA.

So what we are saying is when the patients with lung cancer are picked up in stage IA versus they would without screening at stage IB or IIA or so on and so forth, there would be significant improvement in the survival rate.

Q. But with regard to different size tumors that would be within stage IA, the research reported in this article concludes that improved lung cancer mortality is not demonstrated with a finding of smaller lesions in IA compared to larger lesions in IA.

A. That's what they are saying with stage IA. But I can probably cite 10 references which contradict these findings.

Q. In stage IA?

A. Within stage IA. Not stage IA itself. Just looking at the tumor size, that's our goal.

Q. But I'm talking about IA.

A. Even in stage IA I can probably cite you references.
Q. Please do so.

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A. I don't have them. I will have to go and review my literature. But I will be able to get back to you.
Q. Would you go down to paragraph four of your report?
A. Sure.
Q. Second sentence, "The average survival in lung cancer is 12% contrasted with a survival of 55-70% in stage I disease."
A. That's exactly the point.
Q. Excuse me. Did I read that correctly?
A. Yes.
Q. In this sentence the first portion reads, "The average survival in lung cancer is 12%." Correct?
A. That's correct.
Q. When you used the word "survival," and place it at 12 percent, you are talking about the ultimate survival rate as opposed to a survival rate that would have a five-year limitation; correct?
A. I would think this is in reference to a five-year survival rate. Most of the rates in lung cancer are reported as five-year.

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Q. What's the source of that number?
A. Reference No. 2 and 3.
Q. This is going to be a technical question, which I think I will be able to get right. If not I will try and repeat it.
With regard to the 50 to 75 percent survival in stage I disease, there is no breakdown in stage I disease according to the size of the tumor that is detected; correct?
A. That is usually not broken down in most of the publications that I come across in my experience.
Q. So I'm correct?
A. Yes.
Q. Page two, paragraph 5 at the top.
When I ask you my first question I am not being critical of your grammar. I just want to make sure I understood something.
This first sentence says, "Each year nearly 130,000 cases of new solitary pulmonary nodules are found in the United States."
Are you referring to 130 individuals? In other words, is a case a person or is a case a single nodule? Let me go on from there. You

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will see my question.
In other words, if you yourself would have three solitary pulmonary nodules, that wouldn't constitute three cases, would it?
A. These are patients, 130 patients with solitary nodules. Solitary pulmonary nodule means one nodule.
Q. I understand. I just wanted to make sure we were talking about 130,000 patients.

Your next sentence says, "About 50-60 percent of these nodules are benign."

Did I read that correctly?

A. That is correct.

Q. Does that mean that of all the nodules you find, 50 to 60 percent are benign, or does that mean in 50 or 60 percent of the patients that are seen the nodules are benign?

A. Fifty to sixty percent of the solitary pulmonary nodules which are resected, these data are collected from surgical pathology series. So if the surgeon does surgery on 130,000 of patients with solitary nodules, 50 to 60 percent of the specimens that are sent to pathology are benign. Again, we are dealing with a solitary

pulmonary nodule. It means one nodule in one patient.

Q. I am not expecting a complete list from you in response to the following question. Examples would do.

With regard to the nodules that are removed surgically and determined to be benign, what are some example of the benign conditions detected in those nodules?

A. I will mention some of them when they come to memory at this time.

Granuloma, histoplasmosis, fungal infections, silicosis. It's not a complete list.

Q. Any others? I understand it's not a complete list, and I am not going to claim later that you said it was a complete list. Can you think of any others?

A. Carcinoid. Maybe some cases of pneumonia.

Q. Any others?

A. Oh, you want me to go on? I'm sorry.

Q. If you can think of any.

A. Those are the ones that I can think of

at this time.

Q. These benign conditions you have just described as being found in solitary pulmonary nodules removed at surgery --

A. That's correct.

Q. -- those are benign nodules which would have been observed on chest x-ray or CT scan prior to the performance of the surgical procedure where they were removed; correct?

A. Yes. Now, I would like to qualify my answer.

There are certain things a reader should be aware of. Some of these things are much more common in the Midwest area than in the State of West Virginia, number one.

We have been dealing with these patients since I have been here for six years. And incidents of these conditions, a solitary nodule, in the State of West Virginia is much lower than if you were to go to the to the Midwest, for example, or west.

Q. Let me make a statement, which I don't

think you will have any disagreement with, that has to followup. It's easier than asking a

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bunch of questions.

I live in Cincinnati where there is a huge amount of histoplasmosis. I assume that you are familiar with the fact that histoplasmosis is frequently seen in the Ohio River valley?

A. Yes. But we have not come across many cases of -- we must have done PET scans on close to 1,500 patients up until now in the last five years, or 2000 maybe, and I recall only one or two cases, two or three, of histoplasmosis that we have seen.

Q. In Wheeling, which is on the Ohio River, do you know if in Wheeling they see more cases of histoplasmosis than you would see in your patient population in Morgantown?

A. Our patient population, I should define, is a drawing area of the whole state of West Virginia, including Wheeling and Wheeling Hospital.

Q. So it is your testimony that histoplasmosis is not endemic to the Wheeling area?

A. Not in the population that we see.

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Q. In the middle of paragraph six, see the sentence where it says, "The underlined surmise"?

A. Yes.

Q. That sentence says, "The underlying surmise is that early intervention is more commonly curative in asymptomatic screening identified cancers than would be expected in symptom prompted diagnosed lung cancer."

First of all, did I read that correctly?

A. That's correct.

Q. Second of all, is that your opinion?

A. Yes.

Q. You consider that to be an accurate statement?

A. Yes.

Q. The next sentence says, "If detected in presymptomatic stage, the survival rate for lung cancer is twice that of symptomatic disease."

Do you see that sentence, sir?

A. Yes.

Q. What is the basis for that statement?

A. This statement is based out of the consensus statement issued by the International

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Conference on Prevention in New York in October 1999.

Q. Were you at that conference, sir?

A. Yes. I was.

Q. What data or studies were presented in support of that statement?

A. There were several presentations from Mayo Clinic, from Moffitt Cancer Center, from some of the other presenters, which are compiled in a nice recorded data sort of book, if you

want to call it. Most of the information or all the information is contained in that.
Q. Moffitt, sir, is that in Florida?
A. Moffitt Cancer Center, yes, that is in Florida. That's correct.
Q. Do you consider that the Moffitt Cancer Center is expert in the early diagnosis, care and treatment of lung cancer?
A. There are several well-known, well-recognized investigators. Moffitt Cancer is one them, yes.
Q. Is the Mayo Clinic another one?
A. That is correct.
Q. So the Mayo Clinic is well-recognized

for its expertise in a number of areas, including the early detection, diagnosis and treatment of lung cancer; correct?
A. Yes. So is Columbia University in New York -- or Cornell.
Q. Did you mean to refer to Cornell and Columbia, or were you just referring to Cornell because of the Henschke study?
A. I take back Columbia. It's Cornell, the Claudia Henschke study.
Q. Would you look at the bibliography for your report?
A. Yes.
Q. See No. 6? It's a 1986 publication, Radiology?
A. Yes.
Q. Now, sir, you have cited article numbers, reference No. 6, in support of the first sentence in paragraph No. 6. Did you really mean to cite a 1986 article for a 1999 conference?
A. I think it's a typo. In other words, on page 2 in paragraph 6, the citation that's made No. 6. --

Q. What should it be?
A. It should be number -- Can I look at it?
Q. Yes, sir. Please do.
A. That has been there by mistake. It should be corrected. The reference number 6 should be the proceedings of the International Conference in October '99. This information is from the proceedings of that conference.
Q. But let me make something clear. I am not picking on you because you have an improper reference or typographical error or what. That doesn't make any difference to me.
What I'm trying to find out is what would be the proper citation to the materials to which you would refer.
A. The proper citation is Proceedings of the International Conference on Prevention of Cancer held in October '99.
Q. Do you know how one would obtain copies of those proceedings?
A. Yes.
Q. How?
A. It's available, as a matter of fact, on

the Internet. I don't remember the web address,

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but I would be happy to. Plus all the people who attended the conference got a nice compiled book, which was the proceedings of the International Conference.

Q. Did lawyers go to that conference?

A. I don't know. There were a lot of people. I don't know everybody that was there in the conference.

Q. Were there patients that made presentations or advocacy groups that made presentations?

A. Absolutely. The advocacy group was well-represented.

Q. Is the consensus statement with regard to which you have testified one that was put together by just physicians and other scientists, or did it reflect the input of patients and other advocacy groups, if you know?

A. The consensus statement was issued primarily by the scientists. ALCASE group made presentations on the first day. On the second day it was purely scientists, professionals and investigators, which came up with a consensus statement.

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Q. Did the consensus statement reflect input of non-physicians and scientists, if you know?

A. Not that I know of.

Q. If you would, go down to paragraph 7, the next to the last sentence after the reference to 12. "The lung cancer incidence starts to rise," et cetera.

Do you see that?

A. Yes.

Q. I'm going to read that sentence, and then I'm going to ask you a question about it.

"The lung cancer incidence starts to rise at approximately age 40 and continues to rise until it peaks at about age 75."

First of all, did I read that correctly?

A. That is correct.

Q. You would agree with me, would you not, that increasing age itself is a risk factor for the development of lung cancer; correct?

A. There are similar risk factors, and age is one of the important ones.

Q. The next sentence says, The most important risk factor for lung cancer by far is

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tobacco use (85% of lung cancers are found in smokers)."

Do you see where I read that?

A. That's correct.

Q. What percent of tumors found in the lung are primary lung tumors as opposed to metastatic from some other place in the body, about?

A. That question really depends on what population you are looking at in the study, whatever inclusion criteria. Is it a prospective study, a retrospective study? I

think the data will be all over the place if you don't specify what group you are looking at.
Q. Is there any reason to think that with regard to that issue residents of the State of West Virginia would be any different than residents of any other state in the United States?
A. No.
Q. Going down to paragraph 8, you're talking about the recent international conference. Is that the same conference referred to in paragraph 6?
A. Yes.

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Q. "The recent international conference on prevention of lung cancer issued consensus statement after reviewing currently available data and intensive analysis by international experts in the field of lung cancer and imaging."
Did those international experts include experts from Mayo Clinic and Moffitt?
A. Yes.
Q. Those are the individuals you referred to before?
A. They were not the only ones. They were there also.
Q. In this particular case, because you are not an expert in the area, may I assume that you are not offering any opinions with regard to the advisability or lack of advisability of sputum cytology, EKGs, and stress testing? Correct?
A. I would take exception to sputum cytology, but EKGs and the stress testing, yes.
Q. Are you an expert in those areas?
A. I'm not expert, but I review several of the publications dealing with sputum cytology for screening of lung cancer.

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Q. Let me make sure you understood my question.
I'm not trying to find out what the studies say or don't say. I'm trying to find out whether in this case you as an expert in nuclear medicine are going to be going outside of your field of expertise and giving opinion testimony regarding the necessity or lack thereof of EKGs, stress tests, and sputum cytology, or are you going to leave that to other individuals who will be testifying for the Plaintiffs?
A. I would like to give my opinion based on my knowledge reading so many articles and publications and talking to experts in the field of lung cancer screening about what the utility is for sputum cytology for screening of lung cancer.
Q. I will come back to that in a minute.
You are not going to be giving any expert opinions regarding EKGs or stress tests; correct?
A. That is correct.
Q. With regard to sputum cytology, what is

your belief or understanding with regard to the role, if any, it plays in screening for lung cancer in the year 2000?

A. What my belief is, CT scanning for lung cancer screening is much superior to chest x-ray and sputum cytology that were part of the test used in the workup of initial lung cancer screening used in the eighties and seventies, or fifties and sixties.

Q. Are there any risks in a population of 300,000 people from spiral CT and PET scanning?

A. There are no known risks which would outweigh the benefits. In other words, the radiation exposures are within the limits that are put down by the radiation control agencies. So there are no proven harmful effects of any of these tests when they use the diagnostic tests.

Q. You said the benefits outweigh the risks?

A. Significantly.

Q. If the benefits outweigh the risks, what are the risks to the population that are outweighed by the benefits? What risks are there?

A. There is always a risk of radiation exposure whenever you are using any test that uses radiation. But you should also be aware that the risk is actually less than if you take a flight from here to California, for example. Still you have radiation exposure. So it is all relative. When you look at the relative risks it is negligible.

Q. I need to ask you a question comparing the risk to the flight to California. And I'm not trying to be silly. Okay?

On a flight to California there is a risk of death; correct?

A. Whenever you fly, yes, there is a risk.

Q. Is there a risk of death, irrespective of how small, of patients who are exposed to CT scanning as part of the screening program that you propose? And, if so, how small?

A. I'm not aware of any single death resulting from CT scanning in millions of patients who have undergone diagnostic tests to this date.

Q. Before patients undergo CT scanning of the chest, do they give informed consent in your

institution?

A. When they are undergoing CT scanning with contrast, yes.

Q. How about just regular CTs or spiral CT?

A. Regular CT scanning without contrast may be done without informed consent.

Q. The same with spiral CT?

A. Yes.

THE DEPONENT: Can I ask for restroom break, if it is okay?

MR. WOODSIDE: You, obviously, can. And we are going to try and see

what we can do about lunch. We can take a break now.

(Lunch.)

BY MR. WOODSIDE:

Q. I'm not positive, but I think that I was asking you questions about paragraph 8 of your report.

If you would look over to the last portion of that, I'm going to start and ask a couple of questions about the last two sentences at the end of paragraph 8.

"The consensus opinion was that these

characteristics provide an ideal screening test in the new fast CT examination. At this time, however, there are no estimates of long-term impact on spiral CT on patient survival."

Did I read that correctly?

A. That's correct.

Q. At this time it is correct that there are no long-term studies showing that with spiral CT as a screening device there that there is a reduction in the rate of dying from lung cancer; correct?

A. That is correct. However --

Q. Excuse me, sir. That's all I asked you. That is correct?

A. Can I listen to your question again?

MR. WOODSIDE: Would you repeat the question back?

REPORTER: "At this time it is correct that there are no long-term studies showing that with spiral CT as a screening device there that there is a reduction in the rate of dying from lung cancer; correct?"

A. There has been a study from Claudia

Henschke, as you know, that I mentioned, in Lancet. Now, she is continuing long-term followup on all of those patients.

I have not personally talked to her. I know she intends to publish all of this data. But looking at the results of that study, I would be very surprised if that does not show a favorable outcome for all of those patients who have had surgery following the detection of the CT.

Q. As we sit here today, the long-term aspects of her study have not yet been completed; correct?

A. It's not been out in the literature. I don't know if that's been completed or not.

Q. If it has been completed and if there are any results, you have not seen them; correct?

A. It takes about one or two years for the lead time for the articles to get published.

Q. If there are any long-term results by Dr. Henschke, you have not yet seen them; correct?

A. In the paper, in the publications.

Q. You haven't seen them anywhere, have you?
A. No.
Q. Therefore, at this point in time, there are no published long-term studies that you have seen showing a reduction in death rates long-term from lung cancer; correct?
A. No. That's the wrong implication. I think --
Q. You know of no such studies, do you, sir?
MR. CHERVENICK: I object to the --
A. CT is a diagnostic test. The diagnostic tests do not directly influence the patient survival. It's indirect rate of survival, the impact, number one.
Number two, there are studies showing that CT scanning significantly improves detection of those cancers in the early stage, and which is already documented, that there is improved survival.
Q. Sir, at this point in time --
A. Yes.

Q. -- you have not seen published in the literature any long-term studies on patient CT as a screening device where the data from those long-term studies shows a reduction in dying from lung cancer; correct?
MR. FURR: That's spiral CTs.
Q. Spiral CTs. Correct?
MR. CHERVENICK: Object to the question, because he has answered to the best of his ability.
MR. WOODSIDE: It only requires a "yes" or "no."
Q. You haven't seen any such studies long-term in the literature, have you, sir?
MR. CHERVENICK: Objection.
A. There may have been one or two Japanese studies published in the literature, so I cannot be a hundred percent sure about this.
Q. You yourself have not reviewed any studies, have you?
A. I may not have read those papers in detail, but I may have come across at least one such study from the Japanese. As you know, the Japanese have had spiral CT screening going on

for many years. They are routinely doing it, and there is some recent data in which they have shown the impact of this on patient survival rates.
Q. You know of no studies that are published from American institutions demonstrating that as a result of long-term screening with spiral CT that there is a reduction in the death from lung cancer; correct?
MR. CHERVENICK: Objection.
A. This question cannot be answered just by yes or no. I think there are several things one

has to be aware of.
Q. Let's try it this way.
MR. WOODSIDE: Would you mark this as the next exhibit, please?
(Deposition Exhibit No. 5 marked for identification.)
Q. Doctor, I have handed you a piece of yellow-lined paper with Exhibit 5 down at the bottom.
Do you have that in front of you?
A. Yes.

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Q. On that piece of paper, would you write the name or author of any studies showing the long-term impact of spiral CT on patient survival where the data has demonstrated that there is a reduction in the rate of deaths from lung cancer?
MR. CHERVENICK: Objection. He said there may be some Japanese ones, but he couldn't think of the names right now.
A. I don't have a perfect memory, unfortunately. I can't remember every author whose article I read.
Q. So you can't write anything on that piece of paper, can you?
A. Not at this time. If you would give me 24 hours, I probably would be able to.
Q. As you sit here right, you cannot recall any specific article by author, institution or publication; correct?
A. I can recall. I said I cannot recall the name, but I can recall the study.
Q. Name the study.
A. The title of the studies?

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Q. Yes.
A. Again, I wish I had -- I read hundreds of articles. It is impossible for anybody to remember titles. I probably won't remember the title of my recently-published article myself.
Q. So to bring this to a conclusion, you can't remember the title, you can't remember the author, and you can't remember the journal in which it is published; correct?
MR. CHERVENICK: Objection.
A. It's a recent study from Japanese literature looking at the CT screening -- that's what I remember -- and impact on survival.
Q. Is it a long-term study?
A. Impact on survival rates.
Q. Is it a long-term study?
A. What do you call long-term?
Q. Over five years.
A. It is probably not five years. Again, but definite impact on survival rates. I will, again, have to go back and check whether it is five-year or less.
Q. Does it demonstrate a reduction in the rate of death from lung cancer as a result of

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long-term administration or utilization of

spiral CT?
A. I guess I tried to answer that question. As I was saying, CT is a diagnostic test. It's very difficult. I mean, there are so many variables.
CT scan does not treat a patient. CT scan detects the cancer. There has already been studies showing the CT will pick up cancer when no other test will, very small tumors. It's already known when the tumor is picked up very small in the resectable stage, that will improve the patient outcome and survival rate. So I don't really understand the point of the question.
Q. I'm trying to get you to identify any study which shows that with long-term utilization of spiral CT as a screening device there is a reduction in the rate of death from lung cancer. So far you have been unable to give me the title, author, or journal of any such article; correct?
A. I recall the study, but I don't remember the author name or the title of the paper.

Q. Or the journal?
A. Yes.
Q. With regard to the Claudia Henschke study, I have a number of questions. That is the subject of paragraph 9 of your report; correct?
A. Yes.
Q. I gather that you are familiar with that study; correct?
A. Yes.
Q. As I understand it, there were 1,000 individuals that were the subject of the study that she and her coworkers did; correct?
A. One thousand subjects were screened.
Q. They were screened with spiral CT; correct?
A. That is correct.
Q. If you will go down to the fifth line up from the bottom of the page that has the start of paragraph 9, do you see that where it says "233 vs. 33"?
A. That is correct.
Q. What does the 233 represent?
A. Those were the patients who were

detected on CT with the presence of lung nodules.
Q. As I understand the purpose of this study, the researchers at Cornell were attempting to determine whether you could effectively use CT scanning in asymptomatic patients to diagnose lung cancer; is that correct?
A. I would not call them patients. They were subjects.
Q. Individuals?
A. Yes. Subjects or individuals.
Q. In those subjects, after the spiral CT was performed, 233 were detected to have

pulmonary nodules; correct?
A. That is correct.
Q. After those 233 were detected with lung nodules, additional workup or evaluation was done on those 233 subjects; correct?
A. If it was necessary.
Q. Fair enough. I didn't mean to indicate all. Correct?
Do you know what types of workup were performed on those 233?

A. That varied from patient to patient, and that included high resolution CT or some patients had biopsy procedure done or some had mediastinoscopy or bronchoscopy biopsy done.
Q. I think you spoke a little fast there.
A. I said had mediastinoscopy, or bronchoscopy or needle biopsy.
Q. Were there any other types of modalities that were utilized as part of the diagnostic workup on these subjects after the 233 had been determined to have lung nodules?
A. I left out PET scan also.
Q. How many were determined to have PET scans?
A. How many subjects underwent PET scanning?
Q. Yes.
A. I think a small number, less than five. I don't remember the exact number.
Q. Would that be in the article?
A. Yes. It is in the article. I would think three or four, but I'm not sure.
Q. After the 233 were additionally worked up as necessary, 27 were determined to have

malignant disease; correct?
A. That is correct.
Q. Therefore, subtracting 27 from 233, of the 233 that were originally detected with lung nodules, 206 did not have malignant disease; correct?
A. Were not found to have malignant disease or evidence of malignant disease on followup.
Q. Of the subjects who were determined on spiral CT to have lung nodules, only 12 percent actually had diagnosed lung cancer; correct?
A. On CT.
Let me clarify the whole thing. I think we are getting toward a little confusion here.
Q. I don't think I'm getting confused. But go ahead.
A. Okay. Then that's fine. Go ahead.
Q. Your own report says 12 percent of the 233 subjects with one to six nodules had malignant disease; correct?
A. That's correct.
Q. And 206 did not; correct?
A. Correct.
Q. Therefore, of the 233, approximately 88

percent did not have malignant disease; correct?
A. Correct.

Q. Therefore, there were 88 percent that were false positives; correct?
A. No. That was exactly the confusion that I knew you were heading for.
They were not called malignant on CT. Finding a nodule on CT is not equivalent to a malignant nodule. When there is evidence of growth on sequential CTs, that is when you call it malignant nodules.
Q. When you perform spiral CT on a group of asymptomatic patients, as a result of performing the CT you are going to detect lung nodules which are representative of numerous disease entities; correct?
A. If you perform a CT, a one-time test, CT will be positive or negative for the presence of nodules. That is not synonymous with test positive or negative for malignancy.
Q. I think you and I are now on the same wavelength. Let me follow through on this.
When you perform spiral CT as a screening device on a large number of subjects,

you are going to detect the presence of lung nodules in many of those subjects; correct?
A. Correct.
Q. Many of those lung nodules are ultimately, after further diagnostic workup, going to be determined to be non-malignant; correct?
A. Depending on the protocol. According to the protocol that was used in the study, there was followup CT scans performed at three, six, twelve and twenty-four months. And that's mentioned in the paper.
Now, if there is evidence of increasing size of the nodule, that's when the nodule is considered as malignant. Otherwise, it's not.
Q. But, sir, I didn't ask you that.
When you do spiral CT as a screening device on a large number of subjects, you are going to find in many of those subjects lung nodules which ultimately are not diagnosed as being lung cancer.
A. That is correct.
Q. In some they will be diagnosed ultimately as lung cancer; correct?

A. That is correct.
Q. Indeed, when you do spiral CT screening on a large number of subjects, you are going to detect nodules which in many of those patients are diagnosed ultimately as conditions that are not related to smoking; correct?
A. Yes. Some of those nodules are not related to smoking. That is correct.
Q. Indeed, for instance, if the same percents that Dr. Henschke finds are found in other subjects, close to 90 percent of the nodules that are found when there is initial screening with spiral CT are going to be for conditions that are not related to smoking; correct?

A. Yes.
Q. Would you go over to the next page, please, sir?
A. Page 4?
Q. I guess it's page 4. I don't see numbers on it. But it's the continuation of paragraph nine.
If you will go down six lines from the end of paragraph nine, see where it says, "Since

the study did not provide long-term followup," et cetera?
A. Yes.
Q. I'm going to read that sentence and ask you a question.
"Since the study did not provide long-term followup, the false negative rates still cannot be estimated."
Did I read that correctly?
A. That's correct.
Q. So in this particular report that you signed on August 3, 2000, you stated that the Henschke study did not provide long-term followup; correct?
A. That is correct. In that particular publication.
Q. That's still a correct statement; correct?
A. In that particular publication, yes.
Q. My next question may not be all-inclusive, but that's not important for my question. But you can correct me, if you like.
Among other things in the Henschke protocol, after 233 individuals were detected

with lung nodules, there were followup evaluations of various types of biopsy, including bronchoscopy, needle biopsy, et cetera; correct? You can correct me if I am wrong.
A. No. I don't think this is the way it happened.
As I said, there was an initial CT scan which detected 233 individuals as having nodules. Now, before you go ahead and start having workup and biopsies and all of that, there were followup CTs. That's an important thing to note here, because only after the followup CT showed that this nodule was malignant was further workup and operation or resectable surgery performed.
So it would be wrong to say that all of these were false positives, because all the others were not called malignant on CT, to start with.
Q. A number of patients had biopsies, mediastinoscopy, and bronchoscopy and needle biopsy.
A. In her study none, zero, patients had

biopsy or surgery for benign nodules.
Q. I didn't ask that question.
A. I thought that's what you were asking.

Q. No. Let's start this way. I don't know why it's so difficult.

Did any of the subjects in her study have biopsy, needle biopsy, mediastinoscopy, bronchoscopy? Did any of the 1,000 subjects have that?

A. Yes.

Q. Are there complications and risks associated with mediastinoscopy, bronchoscopy, needle biopsy?

A. Yes. And that's one of the reasons we are saying PET scanning, to avoid all of those risks.

Q. Excuse me. All of those procedures have risks; correct?

A. Yes. They have.

Q. In some of them the risk could even be death, although it would be remote; correct?

A. It's a possibility.

Q. In some instances, after biopsy of whatever type, it was determined that the nodule

was not malignant; correct?

A. I think none of the patients in her -- because I draw your attention to the previous page again.

No, I'm sorry. On the same page, on the page 4, the one where you are looking at, about the seventh or eighth line from the end of the first paragraph, where it says, "One interesting observation in this study was 0 false positive rate as none of benign non-cancerous nodules underwent surgery and only one biopsy of a benign non-calcified nodule was performed."

That's your answer. Only one biopsy.

Q. So at least one patient had a biopsy?

A. Out of 1,000. Not patients, subjects.

Q. Excuse me. At least one subject had a biopsy and it was determined that it was not malignant; correct?

A. I would say only one.

Q. Excuse me, sir. At least one?

MR. CHERVENICK: Object to the question.

A. At least one implies maybe more than one, while we know it is only one.

Q. One?

A. Only one.

Q. Would you go to paragraph 10. The first sentence starts out, "The screening of lung cancer."

Do you see that?

A. Yes.

Q. I may have asked you this before. If I did I don't mean to be repetitive. I just can't remember.

Who is it that you propose to be screened?

A. Which population I'm pertaining?

Q. Yes.

A. I mentioned before all subjects who are smokers with 10-pack-year history and more than

50 years of age.
Q. Thank you.
Go down a couple of lines. Do you see where it says, "Lung cancer remains the leading cause of death," et cetera? Do you see that sentence?
A. Yes.
Q. I want to read that sentence to you and

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I want to ask you a couple questions.
"Lung cancer remains the leading cause of death due to cancer in the state and conceptually it is a disease for which screening approaches are very appealing."
Did I read that correct?
A. That is correct.
Q. When you wrote that sentence you meant to be accurate, did you not, sir?
A. Yes.
Q. As you look at again now, it is an accurate sentence; correct?
A. It is.
Q. The next sentence, "The recommended CT imaging test is particularly appropriate for the State of West Virginia due to probability of high incidence of lung nodules in this population."
First, did I read that correctly?
A. That's correct.
Q. What type of lung nodules in the West Virginia population are you talking about?
A. Solitary lung nodules, known calcified lung nodules which are potentially malignant,

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those are the ones we you talking about.
Q. The next sentence says, "This is due to presence of several risk factors such as high smoking incidence."
Did I read that correctly?
A. That is correct.
Q. What other risk factors were you including when you made that statement?
A. The leading one is smoking.
Q. Sir, that's what your thing says, but it is says "this is due to presence of several risk factors," and I want to know what other risk factors exist that lead to a probability of high incidence of lung nodules in the West Virginia population, other than high smoking?
A. Some of the lesser risk factors I would mention is occupational hazards, for example, coal workers pneumoconiosis, and that includes silicosis, granulomatous infections.
Q. Granulomatous?
A. Yes.
Q. Such as tuberculosis?
A. Tuberculosis is not very common, in my personal experience, in West Virginia.

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Q. Coccidia?
A. Fungal infections, yes.
Q. What types of fungal infections have you seen in your practice in West Virginia?

A. It has been mainly coccidioidomycosis. I would also say sarcoidosis. And I think we talked about some of these before granulomatous, histoplasmosis.

Q. For the population for the State of West Virginia that you're referring to in those sentences, given the fact that there is a significant exposure to coal in the state, would you expect the population to have a greater incidence of non-malignant solitary pulmonary nodules than in the population seen by Dr. Henschke at Cornell?

A. I would not, because you have to understand, again, we are talking about relative proportion. The number of smokers is higher in the State of West Virginia as compared to any other state, number one. Now, it is true the number of non-malignant nodules is also higher. But I think proportionately the number of smokers has much higher or, in other words, is

disproportionately higher than increasing the other risk factors.

Q. Do you have any data that supports your position in that regard?

A. The data comes, for example, if you look at the incidence of smoking around the country versus the State of West Virginia, it is around 23 percent versus 18 percent. There is higher incidence of teenage smoking in the State of West Virginia, higher incidence of smokers.

It is true there is also higher incidence of coal workers' pneumoconiosis to some extent.

Also, my experience is based on looking at all the patients that come with nodules and with CT and PET scanning in West Virginia University hospital.

Looking at all those numbers, the incidence of cancer among lung nodules is pretty high in the State of West Virginia.

Q. Do you know whether it is higher than in the population from which the subjects came in which Dr. Henschke did her work?

A. I think, looking at her incidence of

cancer, which is 20 --

Q. I --

A. Sir, let me finish. I will give you numbers. I'm answering by giving you numbers.

In her series the incidence of cancer was 2.7 percent per 1,000.

We see many more asymptomatic nodules which turn out to be cancer, in my experience, here in the State of West Virginia.

Q. Do you know what the prevalence was of smokers in the population that Dr. Henschke drew from in her study?

A. All those were 20-pack-year smokers. Or 10-pack-year smokers. I take it back.

Q. Can you think of any other risk factors that would result in a high incidence of lung nodules in the West Virginia population other

than the ones you have told me about today so far?
A. No, I can't think of any others.
Q. In looking at a screening program, such as that utilized by Dr. Henschke, one overall effect of the screening population would be to diagnose non-smoking-related disease; correct?

A. There will be certain numbers of non-malignant nodules that will be picked up, yes.
Q. So the answer to my question is yes; correct?
A. I'm sorry. What was the initial wording in your question? I'm sorry.
Q. One effect of the spiral CT screening program such as that utilized by Dr. Henschke would be to diagnose non-smoking-related disease; correct?
A. That will be one of the effects, yes. But the major effect will be picking up early cancers.
Q. Non-smoking-related disease accounted for approximately 90 percent of the nodules found by Dr. Henschke; correct?
A. I don't think I can make an inference like that from a study. We can say that 80-some percent of the nodules were non-malignant which were picked up in smokers. Whether to categorically say whether they were not related to smoking, likely, but I can't conclusively say that since all of those nodules were not even

biopsied.
Q. So it is likely that almost 80 percent of the nodules determined or detected in a screening program such as that utilized by Dr. Henschke would be non-smoking-related disease; correct?
A. I think it is somewhat distorting the facts, though. The goal of the screening program is not to see how many conditions other than cancer were picked up. The goal is to see how many cancers which won't have been picked up otherwise by any of the tests got actually picked up.
Q. Sir, even though that may be the goal, it is true that in performing such a screening program with spiral CT, such as that utilized by Dr. Henschke, there will, indeed, be other conditions which are detected and diagnosed; correct?
A. That is true in any screening program almost.
Q. I agree with you. It turns out that when you are performing a screening program for lung cancer, such as that utilized by

Dr. Henschke, one effect of screening this population would be that in addition to diagnosing lung cancer you are going to diagnose non-smoking-related disease which accounts for approximately 88 percent of the nodules found;

correct?
A. I don't think we are diagnosing non-smoking disease. A lot of those conditions we don't even know the diagnosis, the final diagnosis, number one.
Number two, I have a problem with using the word "effect" of the test. That is an incidental finding, so to say, in the screening study.
Q. Let's assume you have a medical-monitoring program. And let's assume that that program is in effect for the citizens of West Virginia. And let's assume it's for the purpose of determining or diagnosing otherwise not diagnosed as lung cancer. Got me so far?
A. Yes.
Q. If 88 percent of the nodules which are determined to exist are not malignant, many of those patients are going to undergo evaluation

and further workup for those non-malignant nodules; correct?
A. It depends on what you mean by "further workup."
Q. Additional diagnostic work.
A. You don't have to do them. As I said, Claudia Henschke, what she did, she did a followup CT. If you call that a further workup, yes. But if you don't call it, it's not a further workup.
Q. Sir, I'll get back to this in a minute.
Let me ask you some questions about PET scanning. I'm going to ask you a very general question without many details, which will require a very simple answer. And I represent to you I'm going to expand on it to let you explain in the next couple of questions.
A. Okay.
Q. Basically, what I understand you're recommending is that, in addition to CT scanning, there would, in the appropriate subjects or patients, be utilization of PET scans or imaging; correct?
A. That's correct.

Q. So this would be a sequential utilization of different modalities; correct?
A. That's correct.
Q. What would happen first would be there would be the spiral CT. And then if the results of the spiral CT so indicated, there would follow with PET imaging; correct?
A. Not on all nodules.
Again, the size of the nodule has been completely missing from the equation in our discussion, and that's part of the reason for the confusion.
Q. I'm not confused, sir.
A. Okay. Maybe I thought you were. I take it back.
If you look at the size of the nodule, if the nodule is more than two centimeters, the majority of those nodules which are more than

two centimeters and the probability of cancer increases with the size of the nodule. If the nodule is more than three centimeters in size, very few of those nodules are going to be benign. Now, what we are saying, if the nodule is between 6 and 20 millimeters in size, those

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subjects, after initial screening, should undergo PET scanning.

Q. Could you repeat that?

A. Yes.

Q. Only because I got lost in the numbers.

A. That's fine. I will try to make it simpler.

After PET scanning, if a nodule is detected, then we'll divide those subjects into three categories.

Q. Now I am confused.

Would you start in just a minute with spiral CT? You just started with PET then. I think you might have misspoke. Just start with spiral CT.

A. Subjects coming in have initial screening CT exam.

Q. Spiral CT?

A. Spiral CT. Screening CT is spiral CT, what I am proposing.

After a spiral CT you have a nodule. The nodules are divided into three sizes. The nodules less than six millimeters in size, nodules between six to twenty millimeters in

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size, and nodules greater than two centimeters in size, or twenty millimeters in size.

Now if you look at the incidence of cancer in different size of these nodules, you are going see the incidence of cancer is very, very high in all those nodules which are more than two centimeters.

Similarly, if the nodule is less than six millimeters, the incidence of cancer in that is very, very low, and that has been shown by the study with Claudia Henschke, where she looked at the incidence of malignancy in different sizes of the nodules. Ninety percent of the cancer, in her study, were more than two centimeters in size.

Now six to twenty millimeter size nodules, that's where by adding PET scanning after the initial spiral CT you will have the most benefit of this proposed two-modality screening program.

Q. Therefore, you're recommending PET scanning as a followup diagnostic modality for a subset of the patients or subjects who are determined to have nodules on spiral CT, and

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that subset would be for those patients where the size of the nodule on spiral CT is between six and twenty millimeters?

A. That is correct.

Q. Are you suggesting that the PET scan would replace needle biopsies of patients who

are determined to have solitary pulmonary nodules?
A. In a way. In that size, between 6 to 20 millimeter size nodules, some of those would have undergone needle biopsy. Otherwise, yes, the PET scan would replace them. That is what PET is currently used for anyway in the clinical diagnosis.
Q. To the seclusion of needle biopsies?
A. Absolutely. And it is recommended as a standard of care.
Q. By whom?
A. By Healthcare Financial Administration, by the PET assessment group that was put together by the Government and that recommended reimbursement, and by the American Cancer Society.
Q. Is the screening program with spiral CT

with the followup diagnostic evaluation with PET scans, as you are recommending, something that is now being reimbursed by Medicare for diagnosis of lung cancer?
A. Medicare at this time is reimbursing for doing PET scanning in patients with indeterminate lung nodules, less than four centimeters in size. Actually, they are reimbursing for a much larger group of patients than what I'm recommending.
Q. Excuse me, sir. I didn't ask that question.
I'm asking if the combined screening program that you have recommended wherein you have initial screening with spiral CT followed by diagnostic workup with PET scan in certain patients something that is being reimbursed for or would be reimbursed by Medicare?
A. Medicare does not reimburse at this time for screening of lung cancer.
Q. Of any type; correct?
A. That's correct.
Q. You are not aware of any long-term studies where there has been a decrease in the

death rate as a result of initial spiral CT scanning followed by PET scanning in the manner you have proposed; correct?
A. We presented the results of our own study in the June meeting of the Society of Nuclear Medicine. And I will describe those, and I will abstract. If you are interested, I'll give you the reference for that.
Q. I have it with me, sir. That's the stimulation study?
A. No.
This is a study done in long-term outcome of patients with lung nodules that have PET scanning after they were deemed as indeterminate lung nodules on CT, and then underwent treatment or no treatment based on the PET scan findings.
The patient outcome results were excellent. In other words, all those patients

which had resection, they were alive.
Again, we have only had a one-year followup because it's a longitudinal study.
But one year, only one patient had recurrence of the disease. All of those

patients who had surgery done. And all those patients are surviving who had surgery done based on PET scan.
Q. So you would agree with me that a one-year followup does not constitute a long-term study, does it, sir?
A. While it does not, it still is a milestone in lung cancer life chronology of what happens. Lung cancer, as you know, has a finite incidence of one-year mortality.
Q. Excuse me, sir. One-year followup does not constitute a long-term study in medicine, does it, sir?
A. It does not. But in lung cancer context it is a relatively intermediate term, followup.
Q. Intermediate as opposed to long-term; correct?
A. That's correct.
Q. Just so we are clear, a one-year followup does not constitute a long-term study in medicine; correct?
A. At this time, yes.
Q. Therefore, as we sit here today, you do not know of any published long-term studies

wherein there has been initial scanning with spiral CT followed up by diagnostic PET scan where there has a been a decrease in the death rate; correct?
A. The answer is yes. But you have to qualify the answer.
In terms of CT scanning is a diagnostic test. It's not used for treating the patient. It not like you are using a drug and looking at the five-year survival rate following treatment with that drug.
CT scanning impact, spiral CT as a relatively new modality was not available until two or three years ago.
Now the initial studies have all shown that CT scanning picks up a large number of cancers when they are still treatable and detectable. The data of long-term survival rate between different stages is already available.
So, basically, if you do take both these studies together, it is easy to draw the inference that it will make an impact.
Q. Sir, I didn't ask you that. The answer to my question is, you know of no such long-term

studies; correct?
A. I already mentioned to you there is a Japanese study. I take it back.
Q. Involving CT and PET?
A. Not PET.
Q. Excuse me, sir. Let me repeat the question one more time.

As we sit here today, you know of no long-term studies published in the scientific medical literature in which there's been initial scanning with spiral CT followed by a diagnostic evaluation with a PET scan that resulted in a decrease in the death rate from lung cancer; correct?

A. Correct. But I don't think we need it.

Q. That's not what I asked you.

A. That's correct.

Q. Would you go toward the end of paragraph 12 (sic).

A. Yes.

Q. It says, "Thus, the combined modality or PET + CT evaluation of patients with possible co-registered image sets will provide complete and highly accurate anatomical and metabolic

characterization of lung nodules and lymphadenopathy."

Did I read that correctly?

A. You are reading paragraph number 12, or before that? Oh, here, I'm sorry.

Q. Start right here with "thus." I will direct your attention --

A. That's correct.

Q. Co-registered image sets are a combination of transaxial sections of CTs matched up with corresponding sections of the PET scans; correct?

A. It's more than that. It's not only matched up. It is overlaid. So the information from both scans is available in one image slide set, so to say.

Q. Have co-registered image set studies been performed?

A. Yes.

Q. Is the data from them available?

A. We have not published our data.

There are two things. Number one, we routinely perform co-registration at our center. Number two, the data has been published

by other investigators.

Q. Is this data on the combined modality of PET and CT?

A. That is correct.

Q. Where is it published?

A. I will have to provide you the reference. I don't remember the reference at this time. But there are several references where they have overlaid the CT and PET co-registration. And, actually, there are several, several references detailing the methodology of co-registering and the benefit of these.

Q. Are these actual studies which have been performed on large numbers of subjects?

A. On patients?

Q. Yes.

A. Yes. They are available in several of the imaging journals. I will be happy to provide you the references.

Q. Are you aware of any published data demonstrating that with co-registered image sets there is a decrease in the death rate of patients with lung cancer?

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A. I'm not aware of anybody having long-term results. We already talked about that before.
Q. And the reason you're not aware of any long-term results is because the technology has not been available for a sufficient amount of time to have long-term studies performed and reported; correct?
A. That is part of the reason.
Q. Let's go to number 12. I am going to read part of it and ask you a question.
"We have further analyzed the data on the recently published screening study in Lancet."
That's Dr. Henschke's study?
A. That is correct.
Q. "A simulation study was done in order to approximate the size distribution of tumors at the time of detection using the CT only diagnosis strategy."
A. That is correct.
Q. You didn't perform a second or additional independent study with different subjects, did you, sir?

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A. No. And simulation study means that.
Q. I'm getting there. What is a simulation study?
A. A simulation study is a statistical modeling, hypothetical model, that is based on some other initial study.
Q. So the simulation that you did was a statistical or hypothetical study utilizing data previously generated by Dr. Henschke; correct?
A. That is correct.
Q. Go down to the last sentence in this paragraph.
"CT + PET protocol results in early detection of 52 percent of malignant nodules with a gain of every 6.2 life years."
Did I read that properly?
A. That is correct.
Q. Now, sir, this was a result of your simulation study?
A. That is correct.
Q. Did this take into consideration lead-time bias?
A. No.
Q. Your simulation study did not tell you

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whether there would be a decrease in the death rate; correct?
A. That's exactly what it did. It told us how many patient life years you can save if you were to screen all subjects using this two-modality test.
Q. Is that because you would diagnose conditions earlier?

A. That is exactly correct.
Q. If you have a patient who is 50 years old and has a life-expectancy of five years, and the patient has some illness which is anticipated to cause his or her death in five years, if you diagnose that same condition using different modalities at 48 and the patient is still only going to live to be 55 years of age, while there's an increase in the life-expectancy from the point in time when the diagnosis was made, the overall time of death is the same; correct?
A. This is a very hypothetical question. Again, you have to assume. There are certain presumptions in this.
First of all, you are already saying the

patient is already at least 50 years. So the benefit of diagnosing it earlier than what the patient age is at this time doesn't even matter. You're saying the patient at this time is 50 years old and is going to live for five more years with that disease?
Q. Yes.
A. Hypothetically, that patient you would have picked up the disease at the age of 48.
Q. I will change the hypothetical.
Suppose his twin brother or a sibling, you picked up the condition at 48, you haven't changed the actual life-expectancy, have you?
A. You are assuming both siblings have the same --
Q. Yes, sir.
A. That's an unrealistic question. It never happens.
Q. Do you know what lead-time bias is? Do you really know what it is?
A. I already mentioned that it is not corrected for in this.
Q. If you didn't correct for it, what is it that you didn't correct for?

A. It doesn't matter. We did not do the correction for it.
Q. On the same piece of paper, Exhibit 5, can you write down the definition of lead-time bias?
A. The lead-time bias -- Let me try and explain to you.
Q. Can you write down the definition of lead-time bias on Exhibit 5?
A. Sure.
Q. Go ahead.
A. (Witness complies.)
Q. I would like to make sure that I am reading this correctly.
This is what you have written: "Lead-time bias - It is the bias built into the study due to hypothetical detection of disease in the asymptomatic stage. The death rates of disease reported in the literature are based on -- and I believe you struck out "individual"; correct?

A. Yes.
Q. You meant that striking out to be a correction; correct?

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A. It is a strike out.
Q. Right. And you meant that strikeout to be a correction?
A. Yes.
Q. -- are based on mortality rates following the clinical manifestation of the disease."
Did I read that properly?
A. Yes.
Q. How many spiral CT facilities are there in the State of West Virginia right now?
A. At this time we have a spiral CT in West Virginia University Hospital. I believe spiral CT is also available in Charleston, at Charleston Area Medical Center.
Q. Excuse me. What is the name of the facility?
A. Charleston Area Medical Center, CAMC.
But I am also aware of certain other sites which are planning on having it very shortly, within a year. Those will be Huntington, and I think Clarksburg group has either just installed or is installing it very shortly.

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Q. At the present time you know of only two spiral CT units that actually are in place and functioning today; correct?
A. Yes. But, as I said, before the end of the year there will be at least four or five sites in the state.
Q. But at the present time there are only two spiral CT sites in West Virginia; correct?
A. I'm not sure about the Clarksburg site. That may be a third one. I know they were planning to install. I don't know if it's just installed or going to install very shortly.
Q. So you know of two, the one at your institution and the one in Charleston that exist now, and there may be a third one in existence, you're not sure?
A. Yes.
Q. How long does it take to do a spiral CT of the chest?
A. Twenty seconds or less.
Q. At your institution how busy is a spiral CT unit?
A. It is being used all the time.
Q. Is there a wait to use it for

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non-emergency patients?
A. I would not think there is a wait. Maybe a wait for one day. But, again the spiral is used not just for chest CT, for all kinds of CT exams.
Q. I understand.
How many PET scanners are there in the State of West Virginia?
A. We have had a PET scanner in our

University since '95. Now this fall, within the next two months, there are contracts with three mobile companies. I think Wheeling may already have mobile PET one day a week. But we have ourselves contracted five other hospitals in southern West Virginia where PET service will be provided.
Q. How frequently?
A. It will be one day a week in each hospital.
Q. A mobile unit?
A. A mobile unit.
Q. Dedicated PET scanners?
A. That is correct.
Q. All of them?

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A. That is correct.
Q. Any hybrid units?
A. No.
Q. How long does it take to have a PET scan?
A. It depends on --
Q. Whole body.
A. The scan of what?
Q. Whole body.
A. Whole-body PET scanning for a tumor workup?
Q. Yes.
A. That, again, varies, depending on the protocol.
Sloan-Kettering, for example --
Q. Excuse me. I apologize. In the State of West Virginia, at your institution, how long does it take to do a PET scan?
A. We are not talking about time for a screening PET scan now. But I will tell you how long it takes for a PET scan of the whole-body tumor workup as it is now, not for screening. It takes about forty minutes.
Q. How long to do a screening PET scan?

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A. Screening PET, if you just want to know if the chest nodule is malignant or not, it probably could be finished in 10 or 15 minutes.
Q. How many PET scans do you do a year here at Morgantown?
A. I will have to give an approximate.
Q. That would be fine.
A. I would say we do anywhere from five to eight patients a day. So you multiply --
Q. Five days a week?
A. Five days a week. Or I will say four, because we have half-day research sometimes. Four and a half days. So, roughly, what will it come to? I guess we need a calculator.
Q. 25 or 30 or so a week?
A. Yes.
Q. If the screening protocol that you have proposed comes to be, how many PET scans do you believe you would do a week then, how many additional PET scans?
A. Your question is if we are doing a screening PET how many more PET scans we can

do?
Q. In your report, which is Exhibit 2, you

have recommended a screening program, which would include PET scans; correct?
A. That's correct.
Q. If that program is adopted in the State of West Virginia, how many additional PET scans would your institution do per week or per year?
A. We would probably install a new PET scanner dedicated for the screening. In that case, as I said, we can do a screening chest PET scan within maybe say 15 to 20 minutes a patient at the most. So you could do potentially three patients an hour, around 20 patients a day, 20 subjects, I should say.
Q. That would be 100 patients or subjects a week?
A. Yes. A hundred a week. So that will come down to 25,000? Is that correct?
Q. No. A hundred a week would be a hundred times 52 weeks.
A. Oh, okay. So it would be more like 52,000.
Q. What is the charge per scan that you just proposed?
A. As I mentioned, screening PET is not

reimbursed at this time. But since it's a much smaller procedure as compared to the whole body PET scanning, the charge, again, would have to be set. But I would think it would be close to anywhere from $1,000 to $1,500.
Q. So that would be between $1,000 and $1,500 for each of the additional 52 PET scans that would be done per year; correct?
A. That's correct.
MR. FURR: 5,200, not 52.
MR. CHERVENICK: 52 times a hundred.
MR. FURR: 5,200.
MR. WOODSIDE: I'm sorry. 5,200.
BY MR. WOODSIDE:
Q. Sir, if all of those PET scans were done at your institution, your income would probably increase substantially, would it not?
A. No. I am full salaried by the university. My income does not increase based on the number of scans that are performed. I am a full-time employee of the University. I'm not in private practice.

Q. So is it your testimony that to do an additional 5,200 PET scans a year would result in no increased financial benefit to you?
A. Yes. That is my testimony.
Q. With regard to those 52 additional PET scans, would the data be accumulated on those individuals?
A. Yes.
Q. Would the data on those individuals who have PET scans, pursuant to your protocol, if

adopted, be utilized to draw conclusions, write papers, and give professional presentations based upon the results?
A. Based on the long-term followup, yes.
Q. Before West Virginia University could do this screening program that you have recommended, would it have to be presented to the IRB?
A. PET scanning is an approved clinical procedure. It is not mandated to have IRB approval; but if you are planning to publish all the data, it is better to get IRB approval.
Q. Indeed, sir, the chairman of your department would probably demand that you get

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IRB approval; correct?
A. If it is going to be published, yes.
Q. You would certainly intend to gather and publish the data, given the significant number of individuals that would be subject to the PET scans; correct?
A. Yes.
Q. Indeed, if this were to occur and take place in West Virginia, you would probably have the largest database of anybody in the world, would you not?
A. I'm not sure about that. There are several other programs being planned. It's a hypothetical question, too.
Q. You don't know of any that would be larger, do you?
A. I know of Japanese studies in very large numbers doing screening programs and publishing the data of CT. And some of them have started doing PET scanning as well.
Q. But if you were going to do all of these PET scans, are there sufficient trained personnel available?
A. Yes.

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Q. What personnel would be required?
A. The essential personnel that's required for performing PET scans are the technologists. There are nuclear medicine technology programs around the state. Basically, any nuclear medicine technologist can be trained in doing PET scanning after training for a month or so.
Q. This program that you have recommended be adopted in this litigation has not been peer-reviewed, has it?
A. No. I will take that back. We did peer-review the combined modality model paper that was presented in the Society of Nuclear Medicine in June. That was a peer-reviewed meeting, a peer-reviewed presentation.
Q. Generally speaking, sir, when one makes presentations at medical or professional meetings, that does not constitute peer review, does it?
A. Absolutely you are wrong, because all the scientific presentations are peer-reviewed and abstracts are reviewed by three reviewers at least.

Q. Abstracts are?

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A. Absolutely.
Q. So your testimony here today is that your screening program, as you have hypothesized it should exist in the State of West Virginia has been subjected to peer review? That's your testimony?
A. The hypothetical model has been.
Q. The program that you are actually proposing, has it been peer-reviewed by professionals in radiology, in radiation medicine, et cetera?
A. As I mentioned, the program is based on the simulation model, and the paper for that was presented as referenced in my report, and that was peer-reviewed. And there is a reference.
Q. So your position is the simulation was peer-reviewed; correct?
A. That is correct.
Q. I am talking about the proposal that you are actually submitting, that you submitted in this litigation, that you signed on the 3rd of August, has that been submitted to a body of your peers for peer review?
A. The program was embodied in the

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hypothetical model that was presented in the Society of Nuclear Medicine meeting.
Q. So hypothetically it was peer-reviewed?
A. I think it was peer-reviewed. The model was peer-reviewed.
Q. If your program, that is, your screening program, utilizing spiral CT followed by PET scan is used, how many lives are going to be saved in West Virginia?
A. Compared to what?
Q. Compared to not adopting this program in West Virginia.
A. We will have to do calculations for that. As I mentioned -- Do you want me to elaborate?
Q. No. So right now you don't know, do you?
A. There will be several life-years saved.
Q. How many?
A. Several life years.
Q. What's the basis for that?
A. The basis is the model that we did.
Q. The simulated hypothetical model?
A. Yes. It is a statistical model. I

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would not call it a hypothetical model.
Q. Sir, I believe that was your word, not mine.
There are many risk factors for lung cancer; correct?
A. That's correct.
Q. Genetics is one?
A. I'm not sure. I think that should be an epidemiologist's question. I'm not sure about that.
Q. Let me make sure I understand

something.
You would agree with me that there are a number of risk factors for lung cancer, however, just what those are does not fall within your area of expertise. Is that a fair statement?
A. That is correct.
THE DEPONENT: I'm sorry. I would like to take a break again, if possible.
MR. WOODSIDE: That is fine.
(Break.)
BY MR. WOODSIDE:
Q. Doctor, I believe after we went off the

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record you indicated that there was some correction in mathematics that you wished to make.
A. Yes. Basically, that was to do with the number of PET scans that would be done per year, screening PET scans. The number should be, I think, 400 PET scans per week we are talking about, because we are talking about roughly 80 -- I'm sorry, take that back.
Let's start over. The screening PET scan would take 15 minutes. Then in one hour you would be doing four. In eight hours it would be roughly 32 times, if you are working five days a week. It would be 160 a week. So it would be 160 times 52.
Q. As you sit here today, you are aware of no national-level public health agency that has ever made a recommendation that smokers be screened for lung cancer; correct?
A. There have been editorials published by well-respected people in the American Cancer Society, and the consensus statement that came out of the international meeting that was held in October '99. All of those things point out

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that lung cancer screening should now be of benefit using the spiral CT. There also have been studies from Japanese literature showing screening CT is useful.
Q. Doctor, that's not responsive to my question.
You are aware of no national-level American public health agency that has ever made recommendations that smokers be screened for lung cancer; correct?
A. I think the consensus statement is pretty much building up.
Q. Strike that. I move to strike it as not being responsive.
I asked you whether or not, as you sit here today, you are aware of any American national-level public health agency, a public health agency, that has ever recommended that smokers be screened for lung cancer?
A. Perhaps not.
Q. Isn't the answer, No, I do not know of any such?
A. What would you call those recommendations that are published in the

literature?
Q. Do you think those are public health agencies?
A. Public health agencies were there at the international conference.
Q. I'm going to go through this two more, three more, maybe five more times.
You are not aware of any American national-level public health agency that has ever as an agency recommended that smokers be screened for lung cancer; correct?
MR. CHERVENICK: I object. He gave his answer.
A. The implication of this question would be wrong. You have to understand the answer in the whole context. It is a changing, it's a transition time.
Spiral CT wasn't even available, number one.
Number two, Claudia Henschke's study is tearing at everyone and saying the spiral CT is useful in picking up early cancer for screening.
And, also, number three, none of the

agencies ever said that screening of lung cancer recently should not be done.
Q. Sir, I will ask the question one more time.
As we sit here today, it is true, is it not, that no American national level public health agency has affirmatively recommended that smokers be screened for lung cancer; correct?
MR. CHERVENICK: Objection.
A. That statement I read in an editorial written by --
Q. I didn't ask you about editorials.
A. -- by the person in charge of the American Cancer Society and National Cancer Institute. Those are public health agencies.
Q. Have the agencies themselves recommended screening for lung cancer?
MR. CHERVENICK: Objection.
A. I already tried to answer that question, that you have to see that in the whole context of what is happening, what changes have occurred, and what the recent studies have shown.
Q. No federal public health agency in the

United States has ever recommended that smokers be screened for lung cancer; correct?
MR. CHERVENICK: Objection.
That's the same question.
A. As I already tried to answer that, the spiral CT, the accuracy of that, all the studies and the agencies which are represented in the international conference on screening of lung cancer, they all agreed to the consensus statement, that the spiral CT should be used for the screening of lung cancer.
Q. Has the World Health agency ever

recommended that smokers be screened for lung cancer?
A. I'm not well-informed about WHO's recommendations and non-recommendations. I will not make any comment on that.
Q. This is a very specific question.
The safe screening recommendations that you make in your report are recommendations that no federal agency, no state public health agency, no national public health organization, and no international public health organization have made so far; correct?

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MR. CHERVENICK: Objection.
Compound question.
A. The people in charge of recommending such programs were represented in the international meeting of screening, and they agreed with the consensus statement.
Q. See, I'm going to go ask them. Is it your testimony that as a result of those people being present that there are federal health agencies, state public health agencies, national public health organizations and international public health organizations which now agree and recommend the specific screening protocol you have recommended in this case?
A. The specific protocol, I see you saying CT plus PET?
Q. Yes.
A. No. They have not.
Q. That's what I'm talking about, CT plus PET.
A. No, they have not. But they have not said it should not be done, either.
Q. Are you aware of the date today?
A. What's the date today?

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Q. Yes.
A. 21st of August, 2000.
(Deposition Exhibit No. 6 marked for identification.)
Q. Doctor, I'm going to hand you first what's been labeled Exhibit 6, which is an article in the Journal of the National Cancer Institute entitled, "Lung Cancer Mortality in the Mayo Lung Project: Impact of Extended Followup" by Pamela M. Marcus and others, appearing in the August 16th, 2000, Journal of the National Cancer Institute.
First of all, sir, have you had occasion to see that recent publication?
A. No. This is the first time I'm looking at it.
(Deposition Exhibit No. 7 marked for identification.)
Q. Doctor, I'm now going to hand you Exhibit No. 7, which is a press release from the National Cancer Institute dated Tuesday, August 15, 2000, dealing with the study which is reported in Exhibit No. 6, and ask you if you have had occasion to read that?

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A. No.
Q. Recognizing that you have not had occasion to read that, I want to go through a portion of it with you to ask you a few questions.
First of all, you would agree that this publication is certainly a current one?
A. Yes.
Q. I'm going to start with No. 6.
MR. CHERVENICK: Before you start, I'm going to object to any questions on either of these exhibits since the doctor has indicated he has not had an opportunity to read them.
MR. WOODSIDE: Your objection is noted.
BY MR. WOODSIDE:
Q. First of all, would you look at the abstract of the lung cancer mortality article that I have labeled as Defendant's Exhibit 6, and take a minute to read it?
A. One minute to read the whole article?
Q. I said take a minute. First of all, I just asked you to look at the abstract, and then

I didn't mean to limit you to a minute.
A. That would be pretty tough for me to do.
Q. To read the abstract?
A. No. Not yet, I said.
Q. Just go ahead and read the abstract. Then I will ask you questions about it.
A. Okay.
Q. This journal article by Dr. Marcus and others reports on a followup which is known as the Mayo Lung Project; correct?
A. That's correct.
Q. Were you before today aware that the Mayo Lung Project had previously existed?
A. Yes.
Q. This report is an extension of the earlier work; correct?
A. That's correct.
Q. In what is known as the intervention arm group, patients were offered chest x-ray and sputum cytology every four months for six years; correct?
A. That's correct.
Q. The usual care arm group was advised at

trial entry to receive the same test annually; correct?
A. That's correct.
Q. Based upon the data developed as a part of this study, the authors concluded that the chest x-ray and sputum cytology performed in the intervention group, that is, the screening, did not reveal a lung cancer mortality reduction; correct?
A. That's correct.
Q. In other words, in this study the authors concluded that the additional screening in the intervention arm did not result in a

decrease in the death rate due to lung cancer; correct?
A. That is correct. Now, this study is using chest x-rays.
Q. I understand that.
The researchers and authors of this study are from the Mayo Clinic, and the Mayo lung Project is a National Cancer Institute funded randomized control clinical trial; correct?
A. That's correct.

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Q. Would you go to the last paragraph, which is on the last page right before the references.
MR. CHERVENICK: I'm going to object to any questions on the last paragraph unless the doctor reads the entire article.
Q. Doctor, would you read the last paragraph, please, to yourself? Then I'm going to ask you a couple of questions about it.
A. Okay.
Q. I'm going to go through this sentence by sentence and ask you questions.
The first sentence says, "Spiral computed tomography (CT) has been shown recently to identify early lung cancer lesions (31) and may ultimately prove to be a more useful screening modality than chest x-ray."
First of all, did I read that correctly?
A. That's correct.
Q. Do you agree with that statement?
A. I disagree to some extent.
Q. To what extent do you disagree with that?

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A. I disagree with the second part of the sentence, basically. Basically, what it says, spiral CT has been shown to identify early lung lesions. That is correct. But where it is saying ultimately prove to be a more useful screening modality than chest x-ray, I think it has already been proven to be a more useful screening modality than chest x-ray from the study by Claudia Henschke.
Q. Let me go on to the next sentence.
"However, if lung cancer lesions with little or no clinical relevance truly exist, spiral CT will identify them at a rate even higher than that of chest x-ray."
First of all, did I read that correctly?
A. Yes.
Q. You do agree with that sentence, do you not, sir?
A. No. It's a hypothetical. Basically, it's an assumption, and I really would not comment on somebody's speculation. The principal author in this article -- It's a purely speculative sentence. I don't know what

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to make of that, number one.

Number two, he is basing a conclusion on a modality that has not even been tested in the study that he is publishing.

Q. You finished?

A. Yes.

Q. The last sentence, "Before spiral CT is accepted into medical practice, it is critical to determine whether this promising new screening modality ultimately does more good than harm in a randomized, control clinical trial with lung cancer mortality as the end point."

Sir, you do agree with that, don't you?

A. I think to some extent it's already been proven. I don't agree with the randomized, control clinical trial.

I don't think you have to prove, you have to do a study again. It is speculation. It is more like a personal opinion than a conclusion based on the results of this study that's published here. It's a pure speculation and personal opinion by the author, which anybody is entitled to.

Q. They are entitled to their opinion?

A. Sure.

Q. You are entitled to yours?

A. Yes.

Q. Is it your position that a randomized, control clinical trial with lung cancer mortality as an end point has already been performed?

A. I think we don't need to do a randomized control clinical trial with lung cancer to be able to see the spiral CT is already here and a useful screening modality.

Q. So you disagree with the authors from the Mayo Clinic, or this NCI, who performed this National Cancer Institute funded study?

A. No. That's a distortion of my statement. I'm not saying that. This study, first of all, is based on chest x-ray and sputum. It is a long-term followup. There are no results in this study about any CT scanning done for lung cancer screening at all.

First of all, I have not read the whole article. Just reading one paragraph out of an article without reading the whole article may be

very misleading.

Q. Would you look at Exhibit 7. This is a press release issued on Tuesday, August 15, 2000, by the National Institutes of Health, Office of Cancer Communications; correct?

A. That's correct.

Q. This deals with the study we have just been talking about as Exhibit 6; correct?

A. That's correct.

Q. I need to make sure I understand something. The National Cancer Institute, I think, is one of those entities which a couple of minutes ago when I was asking you about organizations that support the screening program

you have suggested, they agree with you? Didn't you say that?
A. Yes.
Q. This is the same institute; correct?
A. That's correct.
Q. Let's look at the first sentence.
"After tracking smokers for 20 years, a large study indicates that a screening for lung cancer with chest x-ray does not save lives."
You agree from that portion of the study

we looked at a minute ago that that's what the study concludes; correct?
A. That's correct.
Q. If you go down to the third paragraph, I'm going to read it outloud, "In their analysis, Marcus and colleagues present compelling evidence that a substantial number of tumors uncovered between 1971 and 1983 in the 9,211 participating men turned out never to cause serious illness or death. In the absence of screening, these tumors would not have been found. Such over-diagnosis can lead to unnecessary worry or, more seriously, to expensive and risky biopsies or surgery."
First, did I read that correctly?
A. Yes.
Q. You would agree with me, sir, would you not, that there can be tumors which turn out never to cause serious illness or death?
A. Benign tumors, yes.
Q. Or even they could be malignant slow-growing tumors; correct?
A. Are there any slow-growing malignant tumors which do not cause death?

Q. Do you know?
A. It's a hypothetical question. It is possible.
Q. It is possible?
A. Yes.
Q. If, indeed, in your proposed program the patients turn out to have substantial numbers of tumors that turn out never to cause serious illness or death, that could lead to unnecessary worry or expensive and risky biopsies or surgery; correct?
A. No. Not correct.
Q. Why not?
A. In our program there will not be benign tumors which will be diagnosed as malignant tumors.
Q. What about the followup by the private physicians in the State of West Virginia, are they going to just let all those lesions you find go and do nothing about any of them?
MR. CHERVENICK: Objection, argumentative.
A. What I'm trying to explain is our program has CT and PET both. If you use these

modalities, the number of those benign conditions or tumors or things which do not

cause harm or death to a patient will be negligible. That's why we proposed the model of CT and PET scan.

Q. The next paragraph, I'll read it.

"Marcus' findings arrive in the middle of a debate over a newer screening technology, spiral computer tomography (CT) scans, and could slow enthusiasm for the scans until they are properly studied, she said."

First of all, do you agree that there is a debate over a newer screening technology, that being spiral CT?

A. Yes. There have been debates.

Q. And there currently is a debate; correct?

A. I think more people are convinced that it is the way to be used for screening.

Q. But we are currently in the middle of a debate, as Dr. Marcus indicates; correct?

MR. CHERVENICK: I object.

A. I would not agree with that, in the middle of a debate. I think the consensus

statement from the screening conference was quite conclusive.

Q. And, sir, that screening conference was probably almost a year ago?

A. There was one in October 2000. There is another one in February 2000.

Q. Excuse me. We haven't got to October 2000 yet.

A. No. There was also one in February of 2000.

Q. So that's six months ago?

A. That's correct.

Q. This press release from the National Cancer Institute is more current.

A. This is a speculative statement.

Q. Excuse me. I'm not finished.

A. Yes.

Q. Is more current?

A. It is published more recently, yes.

Q. Do you disagree with Dr. Marcus' statement as set forth in the press release from the National Cancer Institute which contains her quote, "A significant reduction in death rates is the gold standard for any cancer screening

test. Our followup of the Mayo Lung Project shows that an intense regimen of chest x-rays in the 1970s and 1980s did not meet the standard. Likewise, until spiral CT scans are proven to save lives, they should not be recommended as a cancer screening test. The benefits of any screening test must outweigh the harm."

MR. CHERVENICK: I object. This entire press release is hearsay. It's not a published, peer-reviewed medical article in any way, and it's improper to cross-examine the doctor on it. Furthermore, he never saw it before about ten minutes ago.

Q. Do you disagree with Dr. Marcus'

statement?
A. Sir, all this article is based on an old, antique technology, this chest x-ray, the sputum cytology, which really is not relevant to what we are talking about, using a spiral CT and PET scan.
Q. Do you agree that the benefits of any screening test must outweigh the harm?
A. Yes. I agree with that.

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Q. Do you know of any studies showing that spiral CT scans are proven to save lives?
A. The data from Claudia Henschke's studies, along with the literature review, clearly point out that this modality and the statistical model that we did will save lives.
(Deposition Exhibit No. 8 marked for identification.)
Q. I hand you a copy of Exhibit 8, which is a copy of Dr. Henschke's article. You are familiar with that, I believe?
A. Yes.
Q. Would you show me wherein the authors say that, Our screening saves lives?
A. In her study 25 out of 27 patients with nodules that were detected went into surgery. Those patients would not have had surgery if they had not had a screening CT.
Now, if they had not had a screening CT, ultimately they wouldn't be detected in the early stage, and you know the difference between the survival rates of the early stage and when the cancer is unresectable.
Q. Excuse me. Where in there did

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Dr. Henschke and her colleagues say that their screening procedure saves lives?
A. First of all, you have to read the article. As I said, I have already said that before, this is not looking at the long-term followup of patients of lung cancer screening. This study was looking at the benefit and early detection of lung cancer using spiral CT, and all of this was asymptomatic subjects.
We already know the survival rate is different when the cancer is picked up in stage I when it is resectable, and it is a much poorer prognosis for a survival rate when the cancer is picked up in advanced disease.
All you have to do is add two and two, and the answer is four.
Q. Excuse me, Doctor. I didn't ask you that.
Dr. Henschke and her colleagues in their publication in The Lancet on July 10th ,1999, entitled, "Early Lung Cancer Action Project: Overall design and findings from baseline screening," did not say that using their screening program will save lives. They did not

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say that, did they, sir?
A. Can I read a paragraph from her article to you?

Q. After you answer my question.
A. That answer is to your question.
Q. You can read it, but I'm going to ask you the same question again.
A. That is my answer to your question, sir.
Q. The answer to my question is, You are correct?
A. Yes. She does say that, and I will read it to you.
The first page, in the summary, read the last interpretation. That is the conclusion of her findings.
"Low-dose CT can greatly improve the likelihood of detection of small non-calcified nodules, and thus of lung cancer at an earlier and potentially more curable stage."
Q. Sir, it says "potentially more curable stage." Correct?
A. Yes.
Q. They did not say in their study, If you use our protocol, lives will be saved. Sir,

they did not say that, did they?
A. I think it is very easy to --
Q. I'm not asking you to extrapolate. You cannot find those words in this article, can you?
MR. CHERVENICK: I object to the question. He has answered the question.
A. You have to understand what is the implication of the article.
Q. In the article by Dr. Henschke, which I have labeled as Exhibit 8, you cannot find in there anywhere where the authors specifically and directly and succinctly say, If you use our screening protocol lives will be saved.
MR. CHERVENICK: Objection.
Q. That does not appear in there anywhere, does it?
MR. CHERVENICK: Objection.
A. I think if you try to understand what is written in the paragraph that I read, it is implied in there that there will be lives saved.
Q. I didn't ask you any implications. They did not use those words, did they, sir?

MR. CHERVENICK: Objection.
A. If your question just concerns one particular word --
Q. Yes.
A. I think the whole idea here is what is the meaning of the word.
Q. In this article bearing Exhibit No. 8, by Dr. Henschke and others, they did not specifically use the words and say, If you use our screening protocol lives will be saved. Those words are not used anywhere in there, are they, sir?
MR. CHERVENICK: Objection.
A. What does curable and not curable mean? More curable to me means it will save lives. Now, it may not mean that to you. But I

disagree with you.
Q. Sir, they didn't use the words I used, did they?
A. They used a word which means that.
Q. Potentially --
A. Earlier and potentially more curable stage.
Q. Sir, I'm going to ask you this one more

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time.
Dr. Henschke and others, from the Department of Radiology at Cornell University and from the New York Presbyterian Hospital, in the article appearing in the July 10th, 1999 edition of The Lancet, entitled, "Early Lung Cancer Action Project: overall design and findings from baseline screening," did not specifically state, If the protocol we have used here for screening is used, lives will definitely be saved. They never said that, did they, sir?
MR. CHERVENICK: Objection.
A. I think it is implied.
Q. Sir, I don't care what is implied. Did they specifically state that?
MR. CHERVENICK: Objection.
Q. You can say, No, but I think it is implied, and I will move on. Is it correct that they did not say it, even though you think they may have implied it?
A. I think I have already answered the question, sir.
Q. I'm going to take that answer as an

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indication that you are in agreement that they did not specifically so state.
MR. WOODSIDE: And with that, while I'm not finished with my questioning, I'm tired of asking questions, and I believe Mr. Furr would like to ask a few.
MR. CHERVENICK: Objection, and move to strike the first part of that sentence.

EXAMINATION

BY MR. FURR:
Q. Doctor, my name is Jeff Furr. I represent R. J. Reynolds, and I have a few questions for you.
I will begin by going back to a topic Mr. Woodside asked you briefly about. And that is, on your CV, page 20, under "Research Grants" under number one you have listed, "Principal investigator on combined modality (CT + PET) model for efficient screening of lung cancer screening. To be submitted for NCI funding September, 2000 ($900,000), partly funded by Bristol-Meyers 2000, $150,000."

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Correct?
A. That's correct.
Q. Tell me what type of research it is that you are proposing to do.

A. This research looks at the cost-savings compared using screening in smokers, high-risk population. It is looking at the improvement in the mortality rate and cost-savings of that.
Q. When you say "improvement in mortality rate," what specific questions are you trying to answer about whether or not CT and PET scanning results in improved mortality rates?
A. As I said, this grant has not even yet been submitted, and it is being still worked on by me and by my coinvestigators. And what I tell you today may be changed completely tomorrow.
Q. Well, then maybe I will ask you again tomorrow. But I want to know what you're thinking about today.
A. What I'm thinking as of this time?
Q. Yes.
A. Because it has changed as of yesterday also.

Q. Okay.
A. What we are trying to do, we are trying to quantify the cost-savings doing screening in general population using this model.
Q. I didn't ask you about cost-savings.
A. I'm telling you what the study is proposing to do, sir.
Q. Just a moment, sir.
If you will listen closely to the questions and not repeat a lot of material that you've already stated that's not related to the question, we will get done sooner.
In your earlier question you indicated to me that there are multiple types of issues that you might try to address in this study. One of them had to do with something about cost-savings. You also said you were going to look at the impact of using CT and PET scanning on mortality rates.
A. That's correct.
Q. What I want to know is what it is you are currently contemplating examining, what issues you want to study with respect to CT and PET scanning and mortality rates.

A. As I said, we are still debating about what will be in it specifically. This grant is not finally written yet. That's why it says "to be submitted."
Q. We understand that. I didn't ask you about that. That's not what I asked you. I asked you what you are thinking about asking for $900,000 to study with respect to mortality rates.
A. I don't think we have decided yet.
Q. What are you thinking about asking for?
MR. CHERVENICK: Object to the question.
A. We are still discussing, the coinvestigators, how the grant proposal works. Let me explain to you.
Q. I understand how grant proposals work.

That's not my question.
On your CV, highly relevant to this subject matter, I want to know what you and your coinvestigators are currently discussing with respect to the issues that should be examined regarding mortality and the use of CT and PET scans?

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A. It's not finalized yet.
Q. I understand it's not finalized yet. That's why I said "currently discussing." Go ahead, sir.
MR. CHERVENICK: I object to the question. He has answered it.
MR. FURR: He has not answered it once. That's why the question is being asked.
MR. CHERVENICK: I object --
MR. FURR: I don't want to know whether it's not finalized. I understand it's not finalized, it's not submitted. It's on the CV, and I want to know what is being discussed with respect to what they might research.
MR. CHERVENICK: I object to the question.
Q. Go ahead, Doctor.
A. Number one, the aims of this proposal are still being discussed and not finalized yet.
Number two, as of this time what we are proposing to do is following: Number one, we

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are going to prove that doing CT and PET scanning for screening of lung cancer in high-risk population, that is, smokers in certain age groups, you will have improved survival rate than if you are not to screen, and you will have significant cost-savings of the diagnostic workup.
Again, these are still being debated, and it may be completely changed prior to the submission.
Q. You just said "survival rate." A few moments ago you told me you were going to examine mortality rate, the effect of CT and PET scans on mortality rates.
What is it that you and your coinvestigators are contemplating or have been discussing applying to research with respect to CT and PET scans and mortality rates?
A. One of the coinvestigators is in favor of looking at just the mortality rate. Other coinvestigators are interested in looking at mortality rate and survival rates both. It's still being debated.
Q. I take it that you're discussing

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applying for federal funds from the National Cancer Institute to examine whether or not the use of the protocol of CT and PET scans does change either the mortality rates or survival rates from not using that protocol among

10-pack-year smokers over the age of 50; correct
A. No. That's not correct.
Q. What did I get wrong?
A. You were wrong in saying -- Let me tell you what we are planning again.
Q. First, tell me what I got wrong.
A. You said we are planning to see whether or not this improves the survival rate and cost-savings. That's not the question. The question is to quantify the extent to which the savings will be there and --
Q. I'm not talking about cost-savings. I'm talking about mortality rates.
A. I was coming to that, if you will let me complete, sir.
Number one was cost-savings. Number two was improvement in the survival and mortality rate, which is still being debated among the coinvestigators.

Q. What's being debated?
A. I say that again, and I mentioned it before, whether we should just look at the improvement in the mortality rate alone or mortality rate and survival rates both.
Q. You believe that this is something that the National Cancer Institute should currently fund, don't you?
A. I am hopeful.
Q. I mean, obviously, those are questions for which there are not current answers; correct?
A. There are no answers in terms of what is the extent of the improvement.
Q. If the answer to those questions were known, you wouldn't be asking the National Cancer Institute to give you a million dollars to research it, would you?
A. Again, this is still being debated. We have not submitted any proposal yet. This is a speculative question, whether it will be submitted or not. And there is a further speculation whether it will be funded or not.
Q. Could you answer my question, please?

A. Go ahead, please.
MR. FURR: Read it back, please.
REPORTER: "If the answer to those questions were known, you wouldn't be asking the National Cancer Institute to give you a million dollars to research it, would you?"
MR. CHERVENICK: Objection, because he hasn't asked the National Cancer Institute for a million dollars to research those questions.
Q. Go ahead, Doctor.
A. Our proposal is asking to quantify the extent to which these improvements will be there. Our proposal is not looking at just proving that there will be benefit from this. The proof is already there in the current

literature that CT plus PET model should provide benefit to the patients for lung cancer screening.

Q. That still does not answer my question.

MR. FURR: Would you read it back to him, please?

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REPORTER: "If the answer to those questions were known, you wouldn't be asking the National Cancer Institute to give you a million dollars to research it, would you?"

MR. CHERVENICK: Same objection. Also argumentative, also harassing.

A. Let me be very simplistic in choosing my words this time, and hope you understand.

There is already evidence in the literature that CT plus PET model, as I propose in my report, is the best way for lung cancer screening and will result in detection of lung cancer very early on, period.

Now, we want to go a step further to look at the extent to which the benefit will be there using this model as compared to the scenario when this is not used for screening.

Q. And if it was known, if the extent to which these smokers would be benefited by using CT and PET scans to screen in the manner you will propose was known, you would not be asking the National Cancer Institute to fund your

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research with one million dollars, would you?

A. That is not true at all. If you look at how the research proposals are, you already have pilot data, preliminary data which, to some extent, was summarized in my report, which is a statistical model. And the same data is used as preliminary data in the proposal.

Q. So you're asking the National Cancer Institute to give you a million dollars to study something you already know the answer to?

A. I'm not saying that I'm going to ask. It says "to be submitted." It's still being discussed.

Q. You are thinking about whether you can convince the National Cancer Institute to give you a million dollars to study something you already know the answer to.

MR. CHERVENICK: Objection.

A. We are discussing about it.

Q. Earlier today you told Mr. Woodside that if it were up to you you would ban the sale of cigarettes; correct?

MR. CHERVENICK: Objection.

The record speaks for itself.

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Q. Go ahead, Doctor.

A. It is a purely speculative question.

Q. No, it's not speculative at all, because I'm asking whether you told Mr. Woodside that earlier today. If it were up to you you would ban the sale of cigarettes, wouldn't you?

MR. CHERVENICK: Same objection. The record speaks for itself what his answer to the question was.

A. I think what I said was cigarettes should be banned.

Q. Forget what you told Mr. Woodside. Do you think cigarettes should be banned?

A. Yes.

Q. If it were up to you, would you ban cigarettes?

A. That's a speculative question. I will not answer that.

MR. CHERVENICK: And I object. It's totally irrelevant.

MR. FURR: It's not irrelevant.

Q. If it were up to you, would you ban the sale of cigarettes, Doctor?

MR. CHERVENICK: Objection.

A. It's a speculative question. I will not answer that.

Q. You are refusing to answer the question?

A. It is a speculative question.

Q. Doctor, you are going to answer this question either now or at trial, I can promise you.

I want to know today. I have a right to your answer. If it were up to you, would you ban the sale of cigarettes?

MR. CHERVENICK: Object to the question. It is not relevant to his role as an expert in this case.

Q. Go ahead, Doctor.

A. Before I made the decision, if I were to make it, I will see what kind of cigarettes you are talking about, where are we talking about banning it, all those questions.

Q. If it were up to you, Doctor, would you ban the sale of cigarettes as currently marketed in the United States?

MR. CHERVENICK: Object to the question. It is irrelevant.

A. Which cigarettes?

Q. All cigarettes currently marketed and sold in the United States.

A. Are we talking about all tobacco products or cigarettes?

Q. Do you know what a cigarette is?

MR. CHERVENICK: Objection.

A. Yes, I think I know what a cigarette is.

Q. The question was cigarettes.

MR. CHERVENICK: Let's take a break.

Answer the question, and let's take a break.

A. I think it is a speculative question.

MR. CHERVENICK: Let's just take a break. Don't answer the question.

THE DEPONENT: Can I have a break for 15 minutes?

MR. FURR: Of course.
(Break.)

BY MR. FURR:
Q. Dr. Gupta, during the break, did you and

Mr. Chervenick talk about this case or your deposition?
A. Yes.
Q. What did you discuss?
A. I was asking how long can this go on, what's the time limits, because I wasn't sure how long it can go on, and if it's not finished it will have to be done some other day after 5:00.
Q. Understood. Anything else?
A. That's it, I think.
MR. CHERVENICK: For the record, we were sitting about three feet outside the door here with the door open.
Q. Dr. Gupta, if were up to you, sir, today, would you ban the sale of cigarettes that are made and sold in the United States?
MR. CHERVENICK: Same objection as I've stated the previous 10 times this was asked.
MR. FURR: Because it hasn't been answered. It is going to go beyond the today if you don't let him answer

the question.
MR. CHERVENICK: That's fine. We can go for the next three years. That's fine with me. He is being paid.
Same objection.
A. Here is my stand. Let me tell you. Here is what I feel.
I think that cigarettes should be banned in public places where it poses a risk to other people. I don't really care if somebody chooses to smoke in an isolated place or in a private place.
So that's my stand.
Q. So you would not ban the sale of cigarettes?
MR. CHERVENICK: Object to the question. I think he just answered the question.
MR. FURR: He didn't answer the question.
Q. Go ahead. You would not ban the sale of cigarettes; correct?
A. I would ban the use of cigarettes in public places. That's about it.

Q. The record will reflect this, but I believe that this morning you told us that you believe that adults should not be free to choose to smoke cigarettes.
Have you changed your position on that?
MR. CHERVENICK: Object to the characterization of his testimony this

morning.
Q. Go ahead, Doctor.
A. This is what happened. I believe what I meant to say in the morning was cigarettes have a lot of harms, and I think you can go back in the record I said that. There's a lot of harm in their use. Therefore, they should be banned from smoking in public places. That's what I meant. Okay?
I don't think I ever said they should be banned from smoking in private places. But I think wherever there is a risk to an innocent third person who doesn't choose to be harmed by that, then they should be banned.
Q. Should adults be free to choose to smoke cigarettes in private places if they want to do so?

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MR. CHERVENICK: Object to the relevance to his role as an expert.
A. It depends on the person. I will not choose to smoke myself. But if somebody else does, if he doesn't pose a risk to me, I don't care.
Q. That's really not my question, Doctor.
Do you believe that adults, not yourself necessarily, but that all adults should be free to choose to smoke cigarettes as long as they do so in a manner that does not harm others?
MR. CHERVENICK: Objection, relevance. It's beyond his role as an expert.
A. To be honest, I'm not sure. I'd like to think about it.
Q. You're not sure whether or not adults should be free to choose?
A. Yes.
Q. Dr. Gupta, do you have feelings or beliefs about the companies that manufacture cigarettes in the United States?
MR. CHERVENICK: Objection, relevance.

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A. Feelings towards what?
Q. Companies that manufacture cigarettes.
MR. CHERVENICK: Objection also to the word "feelings."
A. I don't have any direct contact with the companies, so --
Q. That's not what I'm asking you.
A. I told you my feelings about smoking.
Q. Right.
A. I don't think I have any feelings towards people who manufacture cigarettes.
Q. That's the question.
Dr. Gupta, do you think the cigarette manufacturers should forced to fund the medical-monitoring program that you have recommended in this case?
MR. CHERVENICK: Objection, beyond his role as an expert in PET scans and CT scans.
Q. Go ahead.

A. I will have to answer that as a personal answer rather than as an expert.
Q. Answer it however you can.
A. Because I think that should be asked of

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an epidemiologist and a public health person and so on, which I don't have expertise in.
I personally feel that they probably should be.
Q. Why?
A. Because there is direct evidence that cigarettes result in certain diseases which are lethal. So in the defense of those victims, I think it's only practical for the manufacturers to pay for the monitoring program which their product led to.
Q. Do you believe that the manufacturers of food products that have a high fat and cholesterol content should pay for medical-monitoring programs to monitor for cardiovascular disease among consumers that eat and use those products?
MR. CHERVENICK: Objection, beyond his expertise, and irrelevant.
A. I think that's a very general question. There's so many products, and it depends on the content, it depends on what information comes on the package. I think there are multiple factors you have to look at.

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Q. Right.
A. And then decide.
Q. So how is that different than a cigarette manufacturer?
MR. CHERVENICK: Objection, beyond his expertise, and irrelevant.
A. Here is how it is different: Everybody eats food, but everybody doesn't have to smoke. But everybody has to eat food. That's the basic difference, I think.
Q. But why does that put cigarette manufacturers in a category that should fund medical-monitoring programs?
MR. CHERVENICK: Objection.
A. I think I tried to answer that. Food is a consumable item which all human beings have to take. But cigarette-smoking is not necessary to be taken. It's not a consumable item. It's more like a habit, a bad habit.
Q. Do all people have to, for some reason, eat foods that are high in fat and cholesterol content?
A. There are different foods with different contents of cholesterol. I think there are very

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few items which have no cholesterol. So, practically speaking, it is very difficult to have that kind of restriction.
Q. But you will agree with me that there are junk foods on the market that have high fat and cholesterol content and very little nutritional value, wouldn't you?
A. Yes.

Q. Do you believe that the manufacturers of those products should be forced to fund medical-monitoring programs for their consumers?

MR. CHERVENICK: Objection. Beyond his expertise, and irrelevant to his role as an expert.

A. That is a question very different from the field that I work in, but I will try to answer it.

I think some of those items, again, may have to do the same thing as your manufacturers, maybe not all. Again, depending on how much information they provide to the buyers, the consumers. The consumers are very well-informed, and there is no negative advertising against the use of those, then

probably they should not. But if there is, then they should.

Q. You mentioned earlier today that you read the deposition of Dr. David Burns that was taken in this case; correct?

A. Yes.

Q. Did you read his deposition that was taken last April or the one that was taken more recently, or both?

A. It was in April.

Q. In April?

A. Yes.

Q. How did you end up reading that deposition? Was it provided to you? Did you ask for it? How did it occur?

A. It was provided to me by my attorneys.

Q. What were you told about that deposition?

A. I wanted to know more about the case that I'm giving my expert report in and who were the other expert witnesses. Dr. Burns was a prominent figure, I know of him from the literature. So I was interested in reading that.

Q. Have you read his most recent deposition that was taken just a week or so ago?

A. No. I wasn't even aware of it. The ones that I got, I think there are two copies that I have. Copy one and two, I think, are both April 2000.

Q. Are you aware that he has changed some of his recommendations with respect to the medical-monitoring protocol that he would recommend that the Plaintiffs receive in this case?

A. No.

Q. When you read Dr. Burns' deposition, did you find Dr. Burns to be expressing opinions to which you disagreed?

A. I don't recall any.

Q. You know that at least in April 2000 Dr. Burns was recommending that the Plaintiffs in this case receive chest x-rays and sputum cytology to monitor for lung cancer, don't you?

A. No. I think the portion that I read he

mentioned that the spiral CT is a more recent modality and was shown to be much more sensitive and accurate than x-ray.

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Q. You believe that that's what he testified to in April 2000?
A. I think there was a mention of that, if I am not wrong.
Q. How long ago did you read his deposition?
A. This weekend, actually?
Q. This past weekend?
A. Yes.
Q. Did you find Dr. Burns to be expressing any opinion about the use of chest x-rays and sputum cytology as tools to use in medical-monitoring in this case?
A. He mentioned those. But then he also mentioned somewhere in his deposition -- I don't remember exactly where -- where he mentioned the spiral CTs, the newer test which has now become available. And, actually, he mentioned Claudia Henschke's study, now that you say. I distinctly remember having read that.
Q. Let me ask you a few questions about the expert report you filed in this case.
You told us earlier that you drafted this report after discussions with Plaintiff's

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counsel; correct?
MR. CHERVENICK: Objection. That's a mischaracterization of his testimony.
A. No. What I said, and I still maintain, is, this report, the attorneys had to tell me what I'm supposed to do. Okay? That I am supposed to prepare an expert report on screening and what tests would be used.
Then I used all the information that I have out of the articles that I read or had access to in my office or in the library, and that information I used to prepare this.
Q. When were you first contacted about working on this case?
A. I don't remember the date. But if I have to guess, about three weeks ago, approximately.
Q. Three weeks ago?
A. Three or four, yes.
Q. Who contacted you?
A. Susan Clark.
Q. Where does Mrs. Clark work?
A. From South Carolina.

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Q. What did she tell you about this case?
A. She told me that there is a lawsuit about screening of lung cancer in smokers, and since I have experience in that she asked me for my expert report on the matter.
Q. Are you being compensated for your time in the case?
A. Yes.
Q. At what rate?

A. For the deposition or for the report?
Q. For all tasks involved in the case.
A. It's the rate that I always charge in depositions. It's $500 per hour.
Q. How much do you charge to prepare the report?
A. The same.
Q. $500 per hour?
A. Yes.
Q. How much do you intend to charge if you are asked to testify at trial?
A. The same.
Q. How many hours have you worked on the case so far?
A. To prepare the report?

Q. Total.
A. I think close to 10.
Q. What did you do in those 10 hours?
A. Reviewed the literature, wrote up the report, read some new articles, read the deposition of Dr. Burns.
Q. Have you met with Plaintiffs' counsel?
A. Yes.
Q. Who have you met with?
A. I met with Susan Clark and some attorney -- I don't know the name -- from Charleston, West Virginia, and --
THE DEPONENT: I'm sorry. I'm not good at names.
MR. CHERVENICK: Chervenick.
Q. When did you meet with Susan Clark and the unnamed attorney from Charleston, West Virginia?
A. I met with them Friday.
Q. How long did you spend with them?
A. About an hour.
Q. What did you do?
A. They briefed me about what the deposition is about and how long it might take,

so on and so forth.
Q. Did they discuss with you what any of the other witnesses in the case had testified to to date?
A. Dr. Burns.
Q. What did they tell you about Dr. Burns testimony?
A. That he is an epidemiologist from California, and I probably should read his deposition, which I did.
Q. Did they tell you why you needed to read his deposition?
A. To familiarize myself with the epidemiologic aspects of the study and his recommendations.
Q. What else did you do with Susan Clark last Friday?
A. That's it.
Q. One hour?
A. Yes.
Q. When did you first meet Mr. Chervenick?
A. I met this Friday also.

Q. How much time did you spend with him?
A. They were all together.

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Q. Have you prepared any other documents related to this case other than your expert report?
A. Related to this case?
Q. Yes.
A. No.
Q. You indicated to Mr. Woodside this morning that you chose 10 pack-years as the smoking history that would make an individual eligible at least for your recommendation regarding medical-monitoring.
A. Right. That's correct.
Q. Am I correct, Dr. Gupta, that it takes about 20 pack-years of cigarette-smoking to develop a statistically significant risk, increased risk for lung cancer?
A. That's what's been published in the literature, yes.
Q. Do you know of any data contrary to that which has been published in the literature?
A. No. But I think, and this is what I understand, the recommendation for the screening program are a little different from the risk estmates, statistical significance. Because

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screening the goal is to pick up the cancer in asymptomatic stage, early on. And usually --
Q. Excuse me, Doctor. What question are you answering now, because I don't understand how this is responsive to the question I asked.
MR. CHERVENICK: I object to the statement. I think he is responding to your questions.
MR. FURR: No, it is obviously not responsive. It is a speech he wants to make --
MR. CHERVENICK: He certainly feels it is responsive.
MR. FURR: No, he doesn't, because he has already said, No.
A. Am I correct, Doctor, that you know of no data contrary to the published estimations in the literature that it takes about 20 pack-years to develop a statistically significant increased risk of lung cancer?
MR. CHERVENICK: Object to the question unless the doctor can explain his answer.
Q. Go ahead.

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MR. CHERVENICK: If he's not allowed to explain his answer, then he should not have to answer.
A. You're asking me is there any literature which says to the contrary that smoking history less than 20 years?
Q. No, that's not what I am asking. Let me start again.
You have already told me that the published estimates in the literature are that

it takes about 20 pack-years of smoking to develop a statistically significant risk of developing lung cancer; correct?
A. That's correct.
Q. My question is, do you know of any data contrary to the estimates published in the literature in that regard?
A. No.
Q. Dr. Gupta, why do we conduct statistical significance tests when we are estimating relative risk in epidemiologic studies?
A. We estimate that to see the threshold at which definitely the disease is proven, that the difference between that will be higher than can

be based on statistical difference, variability, normal variability.
Q. In other words, we conduct statistical significance tests to provide ourselves some assurance that the elevated risk estimates that we are observing are unlikely to be due to chance alone?
A. That's correct.
Q. This is going to be a little bit awkward, but earlier today in response to some questions from Mr. Woodside you indicated that although you could not name them with any specificity or identify them with any specificity today that you believed you had seen published studies from Japan demonstrating an increased survivability at five years for lung cancer among groups screened with spiral CT scans; correct?
A. Yes. That's what I said, yes.
Q. I want to ask you to provide them to Plaintiffs' counsel, and put them on notice that we are asking that they be provided to us when you do find them, as you volunteered to do so.
A. Okay.

Q. Don't send them directly to us. You need to work through Plaintiffs' counsel. But I want to make sure it is clear on the record that we are asking you to go ahead and find those if you can and provide them to Plaintiffs' counsel so they can give them to us.
Okay?
A. I understand.
Q. Let me ask you to look at Exhibit 7, please, sir, that Mr. Woodside marked. That's the recent press release.
As I understood your testimony today, and you correct me if I got this wrong, but I thought I heard you tell Mr. Woodside that you believed that the consensus statement from the series of recent international conferences on lung cancer screening endorsed the use of spiral CT scans to screen for lung cancer in asymptomatic smokers. Is that correct?
A. That's correct.
Q. You believe that the National Cancer Institute was a party to the formulation of that consensus; is that correct?

A. That is correct.

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Q. How do you explain the statements found in the press release we have marked as Exhibit 7 made by Pamela Marcus of the Biometry Research Group, Division of Cancer Prevention of the National Cancer Institute in light of those statements?

MR. CHERVENICK: Objection in that it's speculative. This witness didn't author it. He doesn't know why the person wrote what they wrote. It is hearsay. It's not a peer-reviewed article. I mean, he has not seen it before today.

A. Pamela Marcus was one of the authors on the study that looks at the chest x-ray in the Mayo Lung Project. That's the other exhibit that I was given.

Now, she was one of the coinvestigators along with the Mayo Clinic people.

What they found in long-term followup with chest x-ray and sputum cytology has no relevance to the use of CT. I understand the statement that's made here, but I think this statement really doesn't belong here because the

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study is done with chest x-ray. It should have no implication in terms of spiral CT.

Q. I understand you think that. Let's back up a little bit.

What is the National Cancer Institute?

A. What is it?

Q. Yes.

A. It's a branch of National Institute of Health.

Q. What are its responsibilities and what is its role?

A. It administers and promotes research in diseases that we don't have treatments for.

Q. The National Cancer Institute is the leading funding and research institution in the United States on cancer; correct?

A. It's one of the leading.

Q. Is there an institute or agency that's more prominent than the National Cancer Institute?

A. The American Cancer Society itself is pretty big.

Q. What is the Office of Cancer Communications at the National Cancer Institute?

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A. I don't know of anybody personally from Cancer Communications, but I would think it is a branch of the National Cancer Institute which communicates information or disseminates the research information to the public.

Q. What is the Biometry Research Group, Division of Cancer Prevention at the National Cancer Institute?

A. I don't know.

Q. In this press release from the National Cancer Institute's Office of Cancer

Communications, Dr. Marcus is quoted as saying, "Likewise, until spiral CT scans are proven to save lives, they should not be recommended as a cancer screening test. The benefits of any screening test must outweigh the harm."
Correct?
A. That's correct.
Q. Does that sound to you like the National Cancer Institute is endorsing the use of spiral CT scans to screen for lung cancer?
MR. CHERVENICK: Objection. It is a hearsay statement. It's been covered.

A. I don't think it's saying that it's not useful.
Q. That wasn't my question. My question was, does it sound to you like the National Cancer Institute is endorsing the use of spiral CT scans for screening in asymptomatic smokers?
MR. CHERVENICK: Same objection.
A. They are not endorsing it, but you have to understand the implication in the whole context. This study was based on chest x-ray and did not show any difference.
Q. That's not what I'm asking about now.
A. That's the context, though.
Q. That's not what I'm asking about.
This says, "Likewise, until spiral CT scans are proven to save lives, they should not be recommended as a cancer screening test."
Correct?
MR. CHERVENICK: Objection. This is one statement from a press release that is quoting a paper --
Q. Is that what it says?
MR. CHERVENICK: I'm not

finished.
-- and it is hearsay and it is not necessarily something that's endorsed by the National Cancer Institute. It's a simply a press release talking about the findings of one paper.
A. At least I would like time to review the whole article.
Q. You're going to have plenty of time between now and trial to review it. But I only have today to ask you my questions.
A. But I'm not ready, sir.
Q. Just give me the best answer you can.
Does that sound to you like the National Cancer Institute is endorsing the use of spiral CT scans?
MR. CHERVENICK: Objection. There is no indication here that the National Cancer Institute is endorsing --
MR. FURR: Please don't make speaking objections. I don't mind form objections, but do not make speaking

objections that instruct the witness how to subsequently answer. We're not going to do that.

MR. CHERVENICK: I'm making the objection I need to make.

MR. FURR: No, you're not going to make speaking objections.

MR. CHERVENICK: I'll make any objection I need to make.

MR. FURR: You're not going to make speaking objections and instruct the witness how to answer.

MR. CHERVENICK: We'll see --

MR. FURR: Other objections are fine, but don't cross that line.

MR. CHERVENICK: I'll make the objection I need to make.

Q. Go ahead, Doctor.

MR. CHERVENICK: Same objection.

A. This study or this press release, at the most, is implying that because there was no long-term improvement in screening using chest x-ray, we have to be careful when we use some of

the new modalities such as CT scanning. That is the most I take it from this press release.

Q. But it goes further than saying be careful. It says they should not be recommended, doesn't it?

A. I don't see that saying anywhere.

Q. Okay. Look in the last sentence, fourth paragraph of the press release.

A. Again, I have not read it.

Q. That's why I'm directing you to it. The first page.

A. First page.

Q. Last sentence, fourth paragraph.

"Likewise, until spiral CT scans are proven to save lives, they should not be recommended as a cancer screening test."

Correct?

MR. CHERVENICK: Same objection as previous.

A. First of all, it's a personal opinion of what Pamela Marcus is saying.

Q. Let's just agree, first of all, on whether or not that's what the document says.

That is what the document says, isn't

it?

A. Yes. The document is quoting --

Q. That's the only question I asked so far.

A. It's a quote.

Q. That's the only question I've asked.

A. It's a quote.

Q. My next question is, does that sound like they are endorsing the use of spiral CT scans to you?

A. Who is "they"?

Q. The National Cancer Institute.

MR. CHERVENICK: Objection.
A. That's what I'm trying to tell you, sir. This is a quote from Pamela Marcus. It is not saying National Cancer Institute. It's saying Pamela Marcus. It's quoting. What she is saying is that we should be careful. Because we had no conclusive results or no benefit from chest x-ray screening, we should be careful in using some other test in the future.
That's her personal opinion. It's one person, I think.
Q. Let's see how personal and how

institutional it is.
The underlying --
MR. CHERVENICK: Objection.
Move to strike.
Q. -- study appeared in the Journal of the National Cancer Institute; correct?
A. Is this study published in the journal?
Q. The underlying study, Exhibit 6.?
A. Can I have that?
Q. You have it.
A. This is 7.
Q. You should have 6 also. It's in the stack right in front of you, Doctor.
MR. CHERVENICK: Objection to any questions on Exhibit 6 since the doctor had not seen this before today.
A. I don't think I have it, sir.
MR. CHERVENICK: I object to him being asked any questions about the study.
Q. The study that appears in Exhibit 6 was published in the Journal of the National Cancer Institute, wasn't it?
A. That's correct.

Q. What is the Journal of the National Cancer Institute?
A. What is it?
Q. Yes.
A. It's a peer-reviewed publication from the Journal of the National Cancer Institute that publishes several articles. It does not necessarily speak for National Cancer Institute. It publishes peer-reviewed articles.
Q. It is the National Cancer Institute's journal, isn't it?
A. Yes.
Q. It publishes peer-reviewed articles?
A. That's correct.
Q. By the way, it is a respected journal, isn't it?
A. It is one of the respected journals.
Q. An important journal on issues related to cancer?
A. It is one of them, but there are several others also.
Q. At what size do lung cancers typically metastasize?
A. That's a very tough question. I wish

anybody would know. It depends. In one person they may metastasize -- I have seen cancer as small as nine millimeters metastasize. And I have also seen a six-centimeter tumor not metastasize.

Q. So you have seen cancers as small as nine millimeters metastasize?

A. Yes.

Q. Is it possible for cancers to metastasize before they are detectable using spiral CT scans?

A. Your question is, is it possible for cancer to metastasize before they can be even detected on spiral CT?

Q. Yes.

A. Spiral CT picks up nodules as small as two to three millimeters.

Q. I understand.

A. So I would find it very, very hard to believe that.

Q. Have you ever seen any data one way or the other?

A. No.

Q. I ask you to turn to be paragraph 10 of

your disclosure.

You state that, "The screening of lung cancer may be especially pertinent in the State of West Virginia. West Virginia is one of the states with highest lung cancer mortality and incidence of smoking."

Then you state, There is already precedence of prevention research been actively undertaken in connection with tobacco research centers."

Correct?

A. That's correct.

Q. What does that last sentence mean?

A. What that means is that a significant benefit can be obtained from preventing lung cancer, and one of the ways of preventing lung cancer is to have a smoking-cessation program.

We in the Mary Beth Randolph Cancer Center, in the West Virginia University, we have a tobacco research which does significant research in different kinds of smoking-cessation programs.

Q. I don't understand. What is it about that smoking-cessation research that you find to

have precedential value for recommending your lung cancer screening protocol? I don't understand the connection.

A. The connection is there, that both are sort of prevention programs. And West Virginia University is known to have very active prevention programs and research to prevent or to minimize deaths from cancer.

Q. You may have answered my question with that last answer. But how does lung cancer screening prevent lung cancer?

A. How does lung cancer screening prevent death?

Q. No. Prevent the incidence of lung cancer, prevent lung cancer from occurring.
A. No. It does not.
Q. That's what I was getting at.
A. Yes.
Q. We go to paragraph 11, you state that, "In addition to CT scanning, PET imaging has been successfully applied for the early detection of lung cancer at our center as well as several reputable sites such as Duke, UCLA, Memorial Sloan Kettering, etc., around the

country."
What types of research or studies are you describing there?
A. If you review the literature, there are several, several publications come out from the centers looking at the accuracy, the sensitivity, the specificity, and staging of lung cancer using PET scanning. Different sizes of lung cancer, so on and so forth.
Q. So am I correct that those are studies that have looked at the capability of PET scanning to identify and result in the diagnosis of cancers at an earlier, smaller stage?
A. That's correct.
Q. Those are not studies that have looked at whether or not that earlier diagnosis impacts mortality or survivability?
A. The studies have looked at the staging of lung cancer using PET. We actually proved that if you manage the patients based on PET findings, the group which used PET scanning has a good one-year followup and survival rate.
Q. That's the one-year followup you have already told us about?

A. Yes.
Q. Have any of these centers that you referenced in paragraph 11 done five-year or long-term followups to see whether or not PET imaging has resulted in decreased mortality or increased survivability among people diagnosed with PET scanning?
A. Probably not. But there might have been one or two abstracts in the meeting. I would not be a hundred percent sure.
Q. You mentioned sputum cytology in response to some questions from Mr. Woodside.
It wasn't clear to me. Are you making any recommendations with respect to whether or not sputum cytology should be included as a component of the lung cancer screening program in this case?
A. No. I'm not recommending that.
MR. FURR: That's all I have.
EXAMINATION
BY MR. HUGHES:
Q. Doctor, I have very few questions for you. I am Ben Hughes. I represent Liggett.
Going back to Dr. Burns, have you talked

to Dr. Burns?

A. No. I have not.
Q. Either about his testimony or his report or anything?
A. No, I have not.
Q. Have you talked to any of the Plaintiffs' expert in this case?
A. No, I have not.
Q. Have you been told by the Plaintiffs' attorneys about the trial that's in October in this case?
A. Yes. I was mentioned about that.
Q. What specifically have you been told?
A. That the date is approximately the 2nd of October.
Q. Anything else?
A. No.
Q. Do you know where the trial is set?
A. No. I don't think I asked or I was told.
Q. Did they tell you when you could expect to be called to testify during the trial?
A. No.
Q. The Charleston attorney that you met

with recently, along with Ms. Clark from South Carolina, was his name Scott Segal?
A. Yes. I'm sorry. I'm not good with names.
MR. CHERVENICK: It wasn't Scott Segal.
Q. Scott Long, does that sound right?
A. I'm not good with names. So I don't know.
Q. That's fine.
You were asked about your own financial gain from this screening program if it was brought to WVU Hospital. You said you personally would not benefit financially.
Do you recall that?
A. That's correct.
Q. You would agree with me that the hospital itself would stand to gain greatly financially if this program were set up by the Court.
Is that a fair statement?
A. I'm not sure about that. I think the CT scanner is already pretty busy.
Q. In other words, if the tobacco companies

were made to pay for all of this screening that you propose, you don't think the hospital would gain from that financially?
A. I don't know.
Q. You don't have an opinion either way?
A. I don't know. I think the patients, the subjects are the ones who are going to benefit the most.
MR. HUGHES: That's all I have. Thank you, Doctor.
EXAMINATION
BY MR. WOODSIDE:
Q. I have one question. Those are usually famous last words for lawyers, but I really do

mean one question.
What are the current limits of resolution of your PET scanner, your CT scanner?
A. CT scanner? Spiral CT?
Q. Yes.
A. It's probably two millimeter.
Q. Do you know that for a fact?
A. Yes.
MR. WOODSIDE: That's all I have.

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EXAMINATION
BY MR. CHERVENICK:
Q. I just have one, also.
You told us the cost of the PET scans. What is the cost of the spiral CT scan of the chest, to diagnose a chest?
A. Right now the spiral CT is not reimbursed for screening, as I mentioned. But for a chest CT exam that's ordered or is done, the Medicare pays $845. I would think the screening cost will be cheaper than that. I think I read somewhere or mentioned somewhere $300 to $500 for a screening CT, we are talking about.
MR. CHERVENICK: That's all I have.
EXAMINATION
BY MR. MICHIE:
Q. I have a few questions. My name is Chris Michie. I represent Phillip Morris.
I'm going to ask you to turn to page 20 of your curriculum vitae again.
Under "Research Grants," No. 1, it indicates that the study that you are proposing

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to do is partly funded by Bristol-Meyers. Is that right?
A. The funding has not been used. We have not carried out the study.
Q. So have you received any money whatsoever to date from Bristol-Meyers?
A. Not yet.
Q. Have you received any indication from Bristol-Meyers that they are going to give you that money?
A. There's been assurance, yes. They have expressed a lot of interest in this screening program, and they have mentioned they would be willing to support it.
Q. Have you sent any documentation, information, proposals to Bristol-Meyers?
A. No. I don't have.
Q. So what are they basing that agreement to give you $120,000 on?
A. It was not a funding that has already been obtained. They were talks about the funding, but we don't have the funding yet.
Q. But you indicated a minute ago that they had assured you that you were going to get

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$120,000.
A. No, nothing is sure.

Q. Nothing is sure?
A. No.
Q. So you're not sure at all whether you are going to get the money from Bristol-Meyers or not; is that right?
A. We're not sure, no. Nothing written.
Q. So what makes you believe and what makes you confident enough to put $150,000 in your CV when you have no assurances whatsoever from Bristol-Meyers for it?
A. First of all, this project has not been submitted anywhere yet. If you look at "A" above No. 1 it says, "Awarded and submitted." So it's more like a submission in terms of what we talked to them. We have not received the funding yet.
Q. You have not submitted anything to Bristol-Meyers either?
A. We submitted in terms of they are familiar with our ongoing rough draft of the screening study.
Q. So you have a rough draft. Has that

been committed to paper?
A. I just mentioned that we are debating and discussing on the coinvestigators and changing the proposal and finishing it. So that's the state it is at.
Q. So you have got something in writing. You mentioned a rough draft.
A. No, I don't have. The rough draft -- I'm sorry. Can you repeat your question?
Q. I'm just trying to understand, Doctor. You said that there was a rough draft that you had, and usually when people use the words "rough draft" there's something in writing.
A. What we do is we have ideas that constantly get changed. I'm sure you understand how the academic place works.
We have meetings among the coinvestigators, and there are suggestions. And we have done some preliminary data. It's in a digital form, but it keeps on changing everyday almost.
Q. Please forgive me. I'm not technologically advanced. When you say it's in digital form what do you mean, on a computer?

A. Yes.
Q. Have you got printouts of that information?
A. It is subject to constant change.
Q. What is the data you just referred to?
A. The preliminary data, the statistical model, simulation model.
Q. Is that the simulation study that you were referring to before?
A. That's correct.
Q. So that's not to do with the forthcoming study that you propose to do for NCI and Bristol-Meyers?
A. It's the preliminary data for the study.
Q. Do you have a rough draft of the

proposal as it stands today in its current form?
A. Sure, I do.
Q. I would request that that be produced to the Defendants.
A. Again, it is going to be changed.
Q. That's fine. Just a current version, Doctor. I would just ask that you produce that to the Defendant. Do you have any objection to giving us that?

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A. I will have to check with all the coinvestigators if they have any objection.
Q. There is no confidentiality agreement covering that?
A. There might be. That's exactly what I'm saying. All the coinvestigators have contributed similar to what I contribute.
Q. Do you recall whether you signed a confidentiality agreement regarding that?
A. I don't recall.
Q. You discussed this meeting that was held in New York in 1999.
A. Yes.
Q. You indicated that there was a consensus statement?
A. Yes.
Q. Was that consensus statement ever reduced to writing?
A. Yes. It is.
Q. Do you have a copy of that?
A. Yes. I do.
Q. Can I ask that you provide that to the Defendants?
A. Sure.

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Q. You would be willing to give us that?
A. Yes.
Q. You also indicated that there was a big book of material that you received?
A. Yes.
Q. Do you still have that in your possession?
A. Yes, I do.
Q. Would you be willing to provide us with a copy of that?
A. I have no objection to that.
Q. Have you ever been sued in a civil case, Doctor?
A. No.
Q. I understand that you have no expertise in disease etiology or causation; is that right?
A. What is your question?
Q. You have no expertise in diagnosing the cause of particular diseases?
A. Do I have any expertise in the cause of a disease?
Q. Yes.
A. I don't understand the question. I am a certified M.D., so, of course, I have expertise

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in the diagnosis of diseases.
Q. Have you ever treated patients for lung cancer and --

A. I don't treat patients. But that doesn't mean I don't have expertise.
Q. Have you ever treated a patient suffering from lung cancer?
A. We treat cancer patients with I-131 treatment in our department, yes.
Q. Have you ever diagnosed the cause of a patient's lung cancer?
A. The question is, have I ever diagnosed the cause of lung cancer in a patient?
Q. Yes.
A. How would you diagnose the cause of lung cancer in a patient?
Q. Have you ever told a patient what caused their lung cancer?
A. I might have mentioned that smoking contributes to lung cancer. That's a well-known fact. Eighty-five percent of lung cancers occur in smokers.
Q. Do you think that screening program without PET scans would be effective?

A. Yes, I do. Combining CT and PET. I'm not saying PET alone.
Q. What I'm asking you is do you think a program without PET scans would be effective?
A. Without PET?
MR. CHERVENICK: Without?
MR. MICHIE: Yes.
A. Your question is, would a screening program without PET be effective?
Q. Yes.
A. It probably would be effective, but I think it would be more effective when you use CT and PET.
Q. Do you understand that the proposed class in this case includes all smokers in West Virginia with a five-pack-year smoking history?
A. I think I was told that.
Q. You indicated earlier that someone needs to smoke for a minimum of 20 years before they get statistically significant increased risk; is that right?
A. That's correct.
Q. So the class of people as limited or defined in terms of people with a five-pack-year

smoking history includes people who are at no increased risk; is that right?
MR. CHERVENICK: Object to the question because it's mischaracterizing what, it is purporting to be building on in a prior question, that's a statistically significant increase.
A. I think I answered that question before. The same question has been asked in the morning. But I can say that again.
Statistically significant incidence is a little different from recommending a screening program. The goal in a screening, as you know, is to pick up very early disease. Most of the time, the cancer has to have been there for a while before the disease manifests.

So you have to kind of backtrack five years in order to have a maximum impact to pick up the cancer very early on when it started. That's the goal of the screening.

Q. But does this class include people who are at no statistically significant increased risk?

A. Not statistically significant risk.

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Q. So the class does include such people?

A. Again, I tried to explain, statistical significance is one thing, and recommending for screening is --

Q. I understand what you explained, Doctor. I'm just asking whether the class defined people who are not at statistically significant increased risk of contracting lung cancer.

A. Probably not. Increased risk, but not statistically significant.

Q. It would include such people who are at no statistically significant increased risk?

A. Yes.

Q. Do you think chest x-rays are a reliable diagnostic tool for detecting lung cancer?

A. I think they are highly insensitive and highly non-specific.

Q. So do you think they are unreliable?

A. I don't think they have the required sensitivity and specificity.

Q. So you would not recommended a screening program --

A. No, I would not.

Q. -- that relied upon chest x-rays?

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A. I would not.

Q. The same question for sputum cytology?

A. Again, I'm not an expert. But reading the literature, I would not.

Q. You earlier indicated that PET scans could pick up different sizes of nodules. Do you remember that?

A. That's correct.

Q. You broke it into nodules between six and twenty millimeters, less than six millimeters, and more than twenty millimeters; is that right?

A. That was the CT scan, not PET scan.

Q. CT scan?

A. Yes.

Q. What would the recommended followup be for someone if the nodule came back a size of less than six millimeters?

A. You have to do a repeat CT at three months, six months.

Q. So there would be no other followup that was done other than a repeat CT, so long as the size of the nodule remains below six millimeters?

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A. That's correct. That's what I would recommend.

Q. The meeting in New York in 1999, did they discuss PET scans at that conference?

A. There was some discussion, yes.
Q. Can you tell me the substance of that?
A. The substance was, yes, it's a very new, very promising test that needs to be combined in some way in the diagnostic workup of patients.
Q. Who, if you recall, said that?
A. I don't think I can come up with a name. I'm sorry. But it was a discussion on Sunday morning also in the breakout sessions, and, also, in the first day, Saturday, when there were several presentations being made. And I recall ALCASE group also brought that up because they were saying they know quite a few patients who were diagnosed and benefited from PET scans.
Q. Could you tell me who at Bristol-Myers you spoke to concerning your proposed study?
A. I'm blocking his name. I can't think of it.
Q. Earlier you mentioned accuracy,

sensitivity and specificity.
Are those elements all important in evaluating the efficacy of a medical-monitoring program?
A. Yes.

MR. MICHIE: That's all I have, Doctor. Thanks very much for your time.
MR. WOODSIDE: Actually, I have one more question.

EXAMINATION

BY MR. WOODSIDE:
Q. With regard to the article by Dr. Marcus and others, which has been labeled Exhibit 6, would you like your own copy to read between now and the time of trial?
A. I think I can pull it down from a literature search now that I know. But if you have one I will take it.
Thank you.
MR. WOODSIDE: I have no further questions.
(Waives reading and signing.)
(The deposition of NARESH C.

GUPTA, M.D. was concluded.)

STATE OF WEST VIRGINIA, To-wit:

I, Johnny Jay Jackson, a Notary Public and Registered Diplomate Reporter within and for the State aforesaid, duly commissioned and qualified, do hereby certify that the deposition of NARESH C. GUPTA, M.D. was duly taken by me and before me at the time and place specified in the caption hereof.
I do further certify that said proceedings were correctly taken by me in stenotype notes, that the same were accurately transcribed out in full and true record of the testimony given by said witness.
I further certify that I am neither attorney or counsel for, nor related to or employed by, any of the parties to the action in which these proceedings were had, and further I am not a relative or employee of any

attorney or counsel employed by the parties hereto or financially interested in the action.

My commission expires the 30th day of September 2004.

Given under my hand and seal this 24th day of August, 2000.

_____

Johnny Jay Jackson
Registered Diplomate Reporter
Notary Public